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CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare Coverage Advisory Committee

November 4, 2004

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland

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Panelists

Chairperson

Ronald M. Davis, M.D.

Vice-Chairperson

Barbara J. McNeil, M.D., Ph.D.

Voting Members

David J. Margolis, M.D., Ph.D.

Brent J. O'Connell, M.D.

Clifford Goodman, Ph.D.

Jonathan P. Weiner, Ph.D.

Jed Weissberg, M.D.

Michael Abecaassis, M.D.

Kieren P. Knapp, D.O.

William F. Owen, Jr., M.D.

HCFA Liaison

Steve Phurrough, M.D., M.P.A.

Industry Representative

G. Gregory Raab, Ph.D.

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Panelists (Continued)

Non-Voting Guest Panelists

Sam Klein, M.D., M.S.

Henry Buchwald, M.D., Ph.D.

Harvey Sugerman, M.D.

Executive Secretary

Kimberly Long

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1 PANEL PROCEEDINGS

2 (The meeting was called to order at
3 8:06 a.m., Thursday, November 4, 2004.)

4 MS. LONG: Good morning and welcome,
5 committee chairperson, members and guests. I am
6 Kimberly Long, an executive secretary for the
7 Medicare Coverage Advisory Committee. The
8 committee is here today to discuss the evidence,
9 hear presentations and public comment, and make
10 recommendations regarding the use of bariatric
11 surgery for the treatment of morbid obesity.

12 The following announcement addresses
13 conflict of interest issues associated with this
14 meeting and is made part of the record to preclude
15 even the appearance of impropriety. The conflict
16 of interest statutes prohibit special government
17 employees from participating in matters that could
18 affect their or their employers' financial
19 interests. To determine if any conflict existed,
20 the Agency reviewed all financial interests
21 reported by the committee participants. The
22 Agency has determined that all members may
23 participate in the matters before the committee
24 today. With respect to all other participants, we
25 ask in the interest of fairness that all persons

1 making statements or presentations disclose any
2 current or previous financial involvement with any
3 company engaged in bariatric surgery or products
4 used in the surgery. This includes direct
5 financial investments, consulting fees, and
6 significant institutional support. If you haven't
7 already received a disclosure statement, they are
8 available at the table outside of this room.

9 We ask that all presenters adhere to
10 their time limits. We have a large number of
11 presenters to hear from today and a very tight
12 agenda, and therefore cannot allow extra time.
13 There is a timer at the podium that you should
14 follow.

15 And now I would like to turn the
16 meeting over to Dr. Steve Phurrough.

17 DR. PHURROUGH: Thank you, and let me
18 also welcome the public as well as the panel. We
19 appreciate your time and efforts to assist us in
20 this particular endeavor. We think this is an
21 important issue. Just to clarify what currently
22 Medicare is considering, we have current coverage
23 decisions on our records about what we do and
24 don't pay for in the arena of bariatric surgery.
25 We made some policy decisions this year that

1 allows us to consider either expanding or
2 contracting that particular coverage. The actual
3 things that we do or don't pay for has not changed
4 and the purpose of this meeting is to get some
5 expert advice on what the evidence demonstrates
6 around the benefits of bariatric surgery in our
7 population, both the over and under 65 population
8 that we have responsibility for.

9 There are obviously a whole host of
10 other issues around the treatment of obesity other
11 than bariatric surgery. We are not addressing
12 those today. If you are here to advocate for
13 these, let me suggest that you save that for
14 another meeting that we will have in the near
15 future around other issues other than bariatric
16 surgery. Today's question is what's the evidence
17 around the use of bariatric surgery, if in fact a
18 patient is determined by their physician to be
19 eligible for that.

20 We will take the information that we
21 receive from the panel today and use that
22 information to determine whether in fact we should
23 open a national coverage determination to
24 potentially change our current coverage policies.
25 That's the purpose of this meeting today, we think

1 it's a very important question for our patient
2 population and we look forward to both input from
3 our guests today as well as the panel discussion,
4 so thank you again.

5 DR. DAVIS: Thank you very much,
6 Dr. Phurrough and Kim. Let me just make a few
7 comments myself and kick off the meeting. I'm
8 Dr. Ron Davis, I am director of the Center for
9 Health Promotion and Disease Prevention at the
10 Henry Ford Health System in Detroit, and pleased
11 to have the opportunity to chair the Medicare
12 Coverage Advisory Committee in this particular
13 meeting, and in a few moments we will go around
14 the table and ask members of the committee to
15 introduce themselves and make any conflict of
16 interest disclosures that might be appropriate.

17 I do want to thank in advance the
18 presenters and CMS staff and others who have
19 reviewed the literature and presented an abundance
20 of information to the members of the committee and
21 who will do so throughout the meeting, and also
22 the members of the committee for their
23 participation. And we do have a rather heavy
24 agenda, no pun intended, so I will do my best to
25 keep us on track as we move through all of the

1 people who have requested the opportunity to
2 address the committee, and still allowing the
3 committee enough opportunity to have full
4 discussion amongst the members of the committee.

5 Then of course we have the questions
6 that we have been asked to answer, which will be
7 taken up toward the end of the meeting and if we
8 have time, we will have open discussion about
9 other topics of interest, areas where more
10 research might be needed, the query that CMS
11 posted on its web site as to whether a registry of
12 persons who have had bariatric surgery might be
13 beneficial, and so on.

14 So, let me now proceed again to
15 introduce myself and to review conflict of
16 interest disclosures for myself. The formal
17 disclosure that I made in writing to CMS staff or
18 by e-mail, I should say, was that no, I have not
19 received financial support from any company
20 engaged in bariatric surgery and I haven't
21 previously served on nor do I currently serve on
22 any advisory committee or panel dealing with this
23 topic, and I haven't been contacted by any party
24 prior to the meeting to discuss today's topic.

25 I do want to make two disclosures,

1 though, that are not addressed by those questions.
2 My institution, Henry Ford Health System does have
3 a bariatric surgery program; however, I have no
4 authority over it, no formal role in it, and I
5 have had minimal contact with it since it was
6 formed. Also, as I mentioned at prior meetings of
7 the MCAC, one of my extracurricular activities is
8 as a member of the board of trustees at the
9 American Medical Association; however, I am not
10 officially representing the AMA at this meeting.
11 Barbara?

12 DR. MCNEIL: I'm Barbara McNeil, I'm
13 vice chair of this organization, this committee,
14 and I am chairman of the Department of Health Care
15 Policy of the Harvard Medical School, a
16 radiologist at the Brigham and Women's Hospital in
17 Boston, and I have no conflicts.

18 DR. MARGOLIS: Hi, my name is David
19 Margolis, I'm a dermatologist and epidemiologist
20 at the University of Pennsylvania. In filling out
21 this form, since they specifically asked, it
22 listed two companies, one was Johnson & Johnson,
23 and I actually gave a lecture on
24 pharmacoepidemiologic techniques to a group of
25 medical people there last year. At the time I was

1 unaware that they had any bariatric products. I
2 have no other conflicts.

3 DR. GOODMAN: I'm Clifford Goodman, a
4 vice president of the Lewin Group, a health care
5 policy consulting firm, background in technology
6 assessment of evidence-based medicine. I have no
7 financial conflicts or other conflicts. I should
8 just mention that last month I moderated an
9 invited round-table examining the safety of
10 bariatric surgery at the Agency for Health
11 Research and Quality; however, this was not an
12 advisory panel, it did not make recommendations,
13 it was a discussion round table only.

14 DR. O'CONNELL: My name is Brent
15 O'Connell, I am a physician with Highmark Blue
16 Cross Blue Shield in Pennsylvania. I have some
17 conflicts. I have been on the Blue Cross Blue
18 Shield Technology Evaluation Center which reviewed
19 this topic and that is in your handouts today. I
20 have no financial interest in the topic. The
21 third thing you need to know is that one company
22 did contact me offering to provide information and
23 assistance, which I declined.

24 DR. WEINER: I'm Jonathan Weiner,
25 professor of health policy management at Johns

1 Hopkins School of Public Health and a health
2 services researcher and outcomes researcher. I
3 have no personal conflict of interest although I'm
4 sure among my 30,000 colleagues at Johns Hopkins,
5 all the treatments are being provided, but I have
6 no involvement in any of that.

7 DR. WEISSBERG: Jed Weissberg. I'm a
8 gastroenterologist at Kaiser Permanente and
9 associate executive director for quality in that
10 organization. Like Brent and Barbara, I served on
11 the Blue Cross Blue Shield TEC which considered
12 this topic but have no financial interests.

13 DR. ABECAASSIS: Mike Abecaassis, I'm a
14 professor of surgery at Northwestern University in
15 Chicago. I have no conflicts of interest. In my
16 department, or the department that I am a part of,
17 there are surgeons that perform bariatric surgery,
18 but I have no issues related to that.

19 DR. KNAPP: I'm Kieren P. Knapp, D.O.
20 I am a family physician, past president of
21 American College of Osteopathic Family Physicians,
22 and I have no conflicts of interest.

23 DR. OWEN: Good morning. I am Bill
24 Owen, I'm a professor of medicine at Duke
25 University, I'm also chief scientist at Wechsler

1 International Health Care, I have no conflicts of
2 interest.

3 DR. RAAB: I'm Greg Raab, an
4 independent health policy consultant. I noticed
5 in the financial interest question that I was
6 given that Johnson & Johnson was specifically
7 mentioned and I wanted to point out that I have
8 performed research for Johnson & Johnson but have
9 no relationship with their businesses that deal
10 with bariatric surgery.

11 DR. KLEIN: I'm Sam Klein, the director
12 of the Center for Human Nutrition at Washington
13 University School of Medicine in St. Louis. I
14 receive research support from TransNeuronics for a
15 multicenter trial that's being conducted in this
16 country, and am also on the medical advisory board
17 of EnteroMedics. I was recently on a panel from
18 the American Society for Bariatric Surgery that
19 evaluated gastric obesity surgery.

20 DR. BUCHWALD: I'm Henry Buchwald, I am
21 professor of surgery at the University of
22 Minnesota, I am a guest panelist and I have been
23 in this field for many years. I am a practicing
24 surgeon as well as a professor of surgery in the
25 field of bariatrics. I am past president of the

1 American Society of Bariatric Surgery and the
2 International Federation of Surgery for Obesity.
3 I've participated in many seminars on bariatric
4 surgery and I consult for Ethicon and
5 Transneuronics, and I have recently been called in
6 a telephone conversation by Blue Cross Blue
7 Shield.

8 DR. SUGERMAN: I'm Harvey Sugerman, I'm
9 emeritus professor of surgery at Virginia
10 Commonwealth University and retired general
11 surgeon. I spent many years doing bariatric
12 surgery. I am currently the president of the
13 American Society for Bariatric Surgery for which I
14 receive some financial funding, as well as editor
15 of a new journal called Surgery for Obesity and
16 Related Diseases for which I also receive
17 financial support. I have also been a member of
18 the surgical advisory board for Ethicon
19 Endosurgery at Johnson & Johnson, and have been on
20 speaker panels supported by U.S. Surgical
21 Corporation. I was an initial investigator with
22 the FDA A trial for INAMED Corporation on the
23 laparoscopic adjustable gastric band.

24 DR. DAVIS: Barbara.

25 DR. MCNEIL: Ron, Brent's remark about

1 Blue Cross TEC reminded me that I also serve on
2 that and was on the panel that reviewed it 14
3 months ago.

4 DR. DAVIS: Thank you everybody, and if
5 anyone thinks of another disclosure that they
6 forgot to make a few moments ago and would like to
7 make later in the meeting, that would be fine.

8 I would also like to let the presenters
9 know in advance that before they make their
10 remarks, we would appreciate any appropriate
11 conflicts of interest disclosures on their part as
12 well.

13 So with that, I think we're ready to
14 proceed with the agenda, and the next item is the
15 CMS summary of evidence and presentation of voting
16 questions. Dr. Ross Brechner.

17 DR. BRECHNER: Good morning. With such
18 a distinguished panel, a fellow like me gets a
19 little bit nervous giving a talk, and it reminds
20 me of the famous scientist who made such a
21 phenomenal discovery that he was paid half a
22 million dollars for a year to get around the
23 United States in a chauffeured car and give his
24 talk in different kinds of cities. Somewhere
25 about two months into this, the chauffeur turned

1 to the scientist and said you know, you've got a
2 pretty easy job. You just drive around, give the
3 same talk time after time, and you make a fortune.
4 Well, the scientist said you know, I worked long
5 and hard for this, and I don't understand what the
6 problem is with you, but I deserve this. And the
7 chauffeur said yeah, but you know, it could be
8 done by anybody. I could do it.

9 Well, they made some kind of
10 arrangement and in the next city the chauffeur was
11 dressed as the scientist and the scientist was
12 dressed as the chauffeur, and the chauffeur came
13 up to the stand and gave a flawless speech and was
14 smiling to himself when the moderator said
15 suddenly, we're going to take questions from the
16 audience. Well, someone raised their hand and
17 they said well, look, if we take this data and we
18 do a three-way analysis of variance and we then
19 take out this confounder and put in this
20 confounder, split this group into four groups and
21 do this and that, et cetera, what would happen?
22 Well, the chauffeur looked at him and said you
23 know, that question is a pretty basic and simple
24 question. In fact, it's so basic I'm going to let
25 my chauffeur answer it.

1 (Laughter.)

2 DR. BRECHNER: With that, I'll get
3 started. I do want to thank everyone on the slide
4 for their health. It was a team effort, we all
5 worked together. In my talk after the
6 introduction, I will be talking about Medicare
7 coverage, the epidemiology of obesity, and then
8 the current mechanisms and types of bariatric
9 surgery. I will follow with our procedure for
10 evidence review and the results, the conclusions,
11 and then finally the questions for the MCAC panel.

12 Obesity in the United States has been
13 on a marked rise for 20 to 30 years until
14 recently, 27 percent of our population is
15 overweight and 34 percent is obese. Treatment for
16 obesity consists of modalities like diet,
17 exercise, life style modification, behavioral
18 modification, medications, some combination of
19 those, or bariatric surgery.

20 Some definitions are in order for the
21 talk. BMI is defined as the body mass index and
22 equals the body weight in kilograms divided by the
23 height in meters squared.

24 Classes of obesity, Class I, 30.0 to
25 34.9 BMI; Class II, 35.0 to 39.9 BMI, and Class

1 III, 40 or more, known as extreme obesity. Morbid
2 obesity is a BMI of 35 or more with at least one
3 comorbidity, or a BMI of 40 or over. And the
4 percent extended weight loss is the weight loss
5 resulting from bariatric surgery divided by the
6 preoperative weight, minus an ideal body weight as
7 designated in standard life tables, times 100 to
8 get the percentage.

9 Now CMS is aware that the rate of
10 bariatric surgery is increasing. CMS desired a
11 review and assessment of evidence including
12 quality. We ultimately want to assure that we
13 have the highest quality of outcomes. In the
14 past, Medicare has paid for treatments for obesity
15 if there was a benefit category for that treatment
16 and if the obesity caused or was aggravated by
17 another disease. We could not pay for obesity
18 treatment if there were no comorbidities.

19 Some of the language for this is up on
20 the board: Although obesity itself is not an
21 illness, it may be caused by an illness. Obesity
22 can aggravate other diseases. And services in
23 connection with the treatment of obesity are
24 covered services when such services are an
25 integral and necessary part of a course of

1 treatment for one of these illnesses.

2 Now the language on the top, obesity
3 itself cannot be considered an illness, this is
4 the language that was removed from the NCD manual
5 in July 2004 by CMS. Now we continue to pay for
6 certain treatments of all kinds if there is a
7 benefit category and if obesity is caused by or
8 aggravated another disease. The types of
9 treatments that we have for obesity that are
10 covered has not changes.

11 Congress, with respect to benefit
12 categories, determines the services that we cover
13 and these categories are listed in the Social
14 Security Act, Section 1861. With reference to
15 obesity, these benefit categories exist for
16 surgery or physician counseling, but they do not
17 include exercise, diet counseling for obesity by a
18 dietitian and obesity drugs.

19 Since 1979, Medicare has had a
20 bariatric surgery policy that may reimburse when
21 it's considered medically appropriate and the
22 obesity is related to a comorbidity.

23 What are some of our next steps for
24 coverage? As Dr. Phurrough mentioned, the public
25 is welcome to submit requests to expand coverage

1 to patients who do not have comorbidities for
2 treatments that have a benefit category. CMS will
3 review the policies to determine if current
4 coverage of bariatric surgery should be modified.

5 The first mechanism for bariatric
6 surgery is restrictive surgery. In restrictive
7 surgery the stomach is mechanically reduced in
8 terms of size so that the amount of food that can
9 be taken in is greatly diminished. In
10 malabsorptive surgery, the stomach is bypassed and
11 the food goes to the small intestine at some level
12 in the small intestine. And then there are
13 surgeries that are combinations of those.

14 Now in vertical banded gastroplasty or
15 VBG, a restrictive kind of surgery, some stapling
16 is done here and a band is placed here, and this
17 small pouch is created. It's hard to fill up your
18 stomach like you used to with a small pouch.

19 In laparoscopic adjustable gastric
20 banding, or LAGB, another type of restrictive
21 surgery, the band is wrapped around the stomach
22 just inferior to the esophagus, creating another
23 small pouch with the same result as the first
24 type. This band can be inflated or deflated
25 depending on the needs of the patient, and it's

1 done through this access port.

2 Now Roux-en-Y, or RYGBP, which is a
3 combination type surgery, there's a transection of
4 the stomach, number one, right here, and then 75
5 to 150 centimeters down the bowel there's a
6 transection and the distal part of that
7 transection, lumen is brought up and anastomosed
8 over here and the proximal part is anastomosed
9 down below, causing malabsorption.

10 The biliopancreatic diversion with
11 duodenal switch, the first thing that occurs is a
12 transection of the bowel just below the stomach
13 and then once again, much further down, there is
14 another transection, and the proximal part of that
15 is brought up to the stomach, and this is called
16 the new duodenum, that's where the word duodenal
17 switch comes from, and then the other end, the
18 proximal end is connected way down close to the
19 ilium to once again create malabsorption. Notice
20 that in this surgery, there is also a resection of
21 the stomach.

22 With respect to the epidemiology, the
23 NHLBI in 1998 published this table and simply put,
24 the message from this table is that as BMIs get
25 higher, the risk for different kinds of illnesses

1 gets higher, and the same thing occurs with weight
2 circumference. So when the two of them are
3 combined, there is even a higher risk. Some of
4 these illnesses are coronary heart disease,
5 hypertension, type 2 diabetes, sleep apnea,
6 certain cancers, and musculoskeletal disorders.

7 Now, in a study by Zizza in North
8 Carolina, the number of females that are obese
9 throughout the state as compared to the number of
10 males at a ratio of ten to nine, almost one, with
11 females being slightly higher.

12 The RAND TA in the late '70s, they
13 reported that from the late '70s to the new
14 millennium, Class I and II obesity showed a 50
15 percent increase. Persons of an age greater or
16 equal to 20, of those persons, 55 percent are
17 overweight or obese. They also reported that the
18 rate of extreme obesity in Class III had
19 multiplied by four between 1986 and 2000.

20 Flegal reported that in persons over
21 the age of 75, the prevalence of a BMI greater
22 than or equal to 35 was 6.4 percent.

23 Buchwald in his meta-analysis reported
24 that the current percent of the U.S. population
25 greater than or equal to 100 pounds overweight is

1 5 percent.

2 Steinbrook reported that for extreme
3 obesity, beginning with the early '90s at 2.9
4 percent prevalence, extreme obesity rose to 4.7
5 percent by 2000.

6 The rate of bariatric surgeries is
7 increasing. When it first started, it was low,
8 less than one per 100,000, in the '90s to 2000,
9 progressed from 2.7 to 6.3 per 100,000, in a study
10 by Pope of the National Inpatient Sample.
11 Steinbrook in the New England Journal of Medicine
12 reported that the number of bariatric surgery
13 cases in 2003 was upwards of 100,000, which
14 translates to a rate of about 30 per 100,000 in
15 the population. In North Carolina in the same
16 study by Zizza, adjusting for other factors, the
17 odds of a female having bariatric surgery as
18 compared to a male was over five to one.

19 Now in our evidence review, we
20 performed literature searches to locate papers on
21 surgery for obesity. We focused and confined the
22 overall search to April 2003 to the present
23 because at the time we started the search, we
24 started this review, the latest TA, the latest
25 technology assessment that we could review was the

1 Blue Cross Blue Shield in June 2003, and we went
2 back a couple of months to allow for the time that
3 they had from completing that data to publishing
4 it. We extended our search back in time for
5 papers on the elderly.

6 We found 22 acceptable papers and we
7 utilized five technology assessments. The
8 technology assessments were the NHLBI assessment
9 in 1998, the one that RAND did for AHRQ which was
10 published recently in 2004, Commonwealth of
11 Massachusetts technology assessment in 2004, the
12 Blue Cross Blue Shield from 2003, along with a
13 technology assessment done by the University of
14 Pittsburgh for AHRQ in 2003.

15 Now the outcomes that we looked at, a
16 list up there, sustained weight loss, short-term
17 mortality, longevity, that is long-term mortality,
18 comorbidities and complications.

19 With respect to the outcome of
20 sustained weight loss, four of our 22 articles had
21 data on sustained weight loss, one on the elderly.
22 Four of five TAs had data on sustained weight
23 loss, but none had data on persons over 65. With
24 respect to the sustained weight loss, there is no
25 data comparing those with comorbidities having

1 surgery to those without comorbidities having
2 surgery.

3 In the NHLBI tech assessment with
4 respect to bariatric surgery, they reported that
5 it was acceptable to use VBG and RYGBP, remember,
6 this is 1998, if the patient has acceptable
7 operative risks, and they also reported that RYGBP
8 showed a greater long-term weight loss than VBG.

9 In this graph, this is about the
10 Swedish Obesity Study for all surgeries combined.
11 The first line, to adjust you, is on control
12 groups. The next three lines are for surgery.
13 The bottom one is gastric bypass. And these are
14 weight changes that they're showing, the weight at
15 start and weight at the finish. Now for all
16 combined surgeries, these three lines, there was
17 weight loss of 20 kilograms on average at the end
18 of eight years but for bypass surgeries, it was
19 eight to nine kilograms more than the others over
20 those eight years. This was a nonrandomized
21 control trial of 37-to-57-year olds and it is
22 still going on.

23 Dolan reported that for BPD, there was
24 a greater weight loss in BPD than in banding, and
25 at two years, showed that it was 64 percent excess

1 weight loss for BPD and 48 percent for banding.

2 Sugerman demonstrated that after five
3 years in persons over the age of 60 having bypass,
4 there was a 50 percent excess weight loss, and in
5 that study he reported at five years a 27 percent
6 absolute weight loss, percent of body weight.

7 Gonzalez in his study of persons over
8 the age 50 having bypass reported that there was a
9 68 percent weight loss at greater than or equal to
10 18 months after the surgery.

11 Regarding short-term mortality, seven
12 of our 22 articles had data on short-term
13 mortality, one on the elderly. Three of the five
14 TAs had data on short-term mortality but none had
15 data on persons over 65. Once again, with respect
16 to short-term mortality, there is no data
17 comparing those with comorbidities to those
18 without comorbidities having surgery.

19 Flum, in a study of Washington state
20 patients, reported that the short-term mortality
21 rate was 1.9 percent overall, in experienced
22 surgeons 0.5 percent, and in inexperienced
23 surgeons defined as a surgeon who had done 19 or
24 fewer cases, it was approximately 6.0 percent.

25 In the meta-analysis by Buchwald, he

1 reported that for restrictive surgery, the
2 short-term mortality rate was 0.1 percent, for
3 bypass 0.5 percent, and for BPD/DS, 1.1 percent.

4 And Sugerman in his article on bypass
5 surgery in persons over the age of 60, in 80
6 patients had no mortality, representing a
7 short-term mortality rate of 0.0 percent, that's
8 no short-term mortality.

9 Pope, in his study of the National
10 Inpatient Sample, demonstrated that the rate for
11 short-term in-hospital mortality was 0.37 percent,
12 and that stayed the same from 1990 to 1997. This
13 seems to be confirmed by Fernandez, who found
14 in-hospital mortality rate of 0.4 percent in his
15 study.

16 In the Massachusetts technology
17 assessment, they reported that the short-term
18 mortality rate for LAGB was less than 0.5 percent,
19 for VBG less than 1.4 percent, and overall 0.1 to
20 2.0 percent.

21 In Herron's review, he reported that
22 for BPD the short-term mortality rate was 0.5
23 percent to 2.5 percent, and for all the other
24 surgeries 0.0 to 1.0 percent.

25 Fernandez reported risk factors for

1 short-term mortality, including preoperative
2 weight being higher, age being higher, and being
3 male gender.

4 With respect to longevity, there were
5 two out of our 22 articles that had data on
6 longevity, and one on the elderly. Zero of the
7 five TAs had data on longevity, none had data on
8 patients over 65. With respect to longevity,
9 there is no data comparing those with
10 comorbidities having surgery to those without
11 comorbidities having surgery.

12 Now in a study that was a nonsurgical
13 modeling by Fontaine in the New England Journal of
14 Medicine, the years of life lost were measured,
15 and for a BMI of 40 as compared to a BMI of 24,
16 black males had more years of life lost than white
17 males and white females and black females. This
18 varied as the BMI increased. This is for 40, but
19 it went, the years of life lost increased for
20 higher BMIs across all ages and at an older age,
21 the effect decreased markedly and in fact at age
22 60, black females actually in his modeling had an
23 advantage, they gained years of life.

24 Now in Flum's study he showed that
25 there was a longevity benefit if the patients

1 survived to one year after surgery and if that
2 happened, they had a 33 percent lower hazard
3 ratio.

4 Regarding comorbidities, nine of our 22
5 articles had data on comorbidities, one, or two of
6 them on the elderly; there is actually two of
7 them. Three of five TAs had data on comorbidities
8 but none over the age of 65.

9 In Pope's National Inpatient Sample,
10 from 1990 to 1997, in 1990 20.8 percent showed at
11 least one comorbidity and in 1997, 31.4 percent
12 showed at least one comorbidity.

13 In Residori's study, he found that
14 there was at least one pre-op metabolic
15 comorbidity in 57 percent of his patients.

16 Gonzalez in his study of persons
17 greater than or equal to 50 years of age, 90
18 percent had at least one comorbidity. Resolution
19 of those comorbidities was as high as 90 percent,
20 although a little lower for hypertension at 56
21 percent. Of note is the fact that one-third of
22 the diabetes mellitus cases and one-half of their
23 hypertension cases that they diagnoses were
24 previously undiagnosed.

25 In Sugerman's study of persons over the

1 age of 60, he reported that there were 3.8
2 comorbidities per patient, as compared to 2.4
3 comorbidities per patient for those persons under
4 the age of 60.

5 In the Swedish Obesity Study, the odds
6 for developing diabetes mellitus was six times
7 higher over the same period of time in no surgery
8 controls as compared to persons that had surgery.
9 Now with respect to hypertension, that was a more
10 equivocal, there were more equivocally equal, and
11 you can see these two numbers here, but when they
12 looked at the RYGBP patients, there was an
13 improvement in hypertension in the surgical group
14 as compared to the control group.

15 In Dixon's Adelaide study, he reported
16 that just under 50 percent of all the
17 comorbidities that he found improved or resolved.
18 He also reported that 60 percent of patients that
19 had any comorbidity were medication free at three
20 years after surgery.

21 In the meta-analysis by Buchwald for
22 all types of surgery, diabetes mellitus resolved
23 in 77 percent, or improved or resolved in 86
24 percent. Hypertension resolved in 62 percent, or
25 improved or resolved in 78 percent.

1 Hyperlipidemia improved in 78 percent. And
2 obstructive sleep apnea improved or resolved in 83
3 percent. Now, for individual surgeries in that
4 same meta-analysis, he reported that BPD had
5 almost a 99 nine percent resolution of
6 comorbidities, in RYGBP that figures was 84
7 percent, and in banding it was 48 percent.

8 In Dolan's study comparing BPD to LAGB,
9 he reported that the resolution of comorbidities
10 was similar after both procedures, 66 percent
11 hypertension to 100 percent in obstructive sleep
12 apnea or OSA.

13 On the outcome of complications, five
14 of our 22 articles had data on complications, two
15 on the elderly. Three of five TAs had data on
16 complications, but none had complications solely
17 in persons over 65. With respect to
18 complications, there is no data comparing those
19 with comorbidities having surgery to those without
20 comorbidities having surgery.

21 The complication rate in LAGB was lower
22 than other procedures as stated in the
23 Massachusetts technology assessment. Dolan
24 reported in his study a complication rate of 56
25 percent in BPD versus a 6.3 percent complication

1 rate in LAGB.

2 Herron in his review reported that
3 bypass surgery had lower reoperative rates, and
4 Pope reported that those reoperative rates for
5 RYGBP was 1.6 percent, for LAGB 7.7 to 10 percent,
6 for VBG 11.3 percent, in his National Inpatient
7 Samples analysis.

8 The Massachusetts technology assessment
9 reported that LAGB had lower wound infection rates
10 than other surgeries.

11 Felix reported that in all laparoscopic
12 cases, there was a conversion rate to open on 3
13 percent of the cases and that the risk factors for
14 such conversion were higher age, higher weight,
15 and being male.

16 Fernandez reported that the risk
17 factors for leak after surgery were being male,
18 having diabetes or having had a laparoscopic RYGBP
19 versus an open RYGBP.

20 And the RAND TA reported that wound
21 infection rates ran from 2.3 percent for
22 laparoscopic procedures to 11.4 percent for open.

23 Livingston reported that the
24 malnutrition prevalence after surgery was 2.5
25 percent VBG, 16.9 percent RYGBP, and 5 percent

1 overall.

2 With regards to frequency of
3 complications in hospital, the risk factors for
4 complications is reported by Livingston for being
5 of higher age and being male. The most common
6 complication he found in hospital was pneumonia,
7 2.6 percent.

8 In Pope's study, of the NIS from 1990
9 to '97, he reported that dehiscence after surgery
10 decreased from 2.2 percent to 1.4 percent between
11 those two years, and respiratory complications
12 decreased from 7.4 percent to 5.9 percent.

13 In the RAND TA they reported that
14 laparoscopic procedures have fewer wound
15 infections and incisional hernias than the other
16 procedures.

17 Conclusions. There is a paucity of
18 data comparing those with comorbidities having
19 surgery to those without comorbidities having
20 surgery.

21 Weight loss via surgery may be an
22 attainable goal.

23 Combination procedures show greater
24 weight loss than purely restrictive procedures.

25 Sustained weight loss may resolve or

1 improve comorbid conditions.

2 Short-term mortality is between 0.5
3 percent and 2.5 percent, or let's say less than
4 0.5 percent. Experienced surgeons have a lower
5 rate of short-term mortality.

6 Laparoscopic procedures have fewer
7 complications than open procedures. LAGB may have
8 the lowest complication rate.

9 The data on the Medicare population
10 aged 65 or more is sparse, especially outcome
11 data. There is little data on precise numbers of
12 patients with one or more comorbidities in many
13 studies. What we need from here on out are high
14 quality studies on clinically important gaps.

15 Now for the questions for the
16 committee. There are two sets of questions; the
17 first five questions apply to the persons with
18 obesity who have at least one or more comorbidity.
19 The second set will apply to persons who have no
20 comorbidities and have obesity.

21 Question one. How well does the
22 evidence address the effectiveness of bariatric
23 surgery in the treatment of obesity in patients
24 with one or more comorbidities, compared to
25 nonsurgical medical management?

1 How confident are you in the validity
2 of the scientific data on the following outcomes?
3 Sustained weight loss, long-term survival,
4 short-term mortality, comorbidities.

5 How likely is it that bariatric
6 surgery, including RYGBP, banding and BPD will
7 positively affect the following outcomes in obese
8 patients with one or more comorbidities compared
9 to nonsurgical medical management? Weight loss
10 sustained, long-term survival, short-term
11 mortality, and comorbidities.

12 Four, how confident are you that the
13 following bariatric surgeries will produce a
14 clinically important net health benefit in the
15 treatment of obese patients with one or more
16 comorbidities? And the three different surgeries
17 are listed with both an open and lap option.

18 Based on the scientific evidence
19 presented, question number five, how likely is it
20 that the results of bariatric surgery in obese
21 patients with one or more comorbidities can be
22 generalized to, A, the Medicare population aged 65
23 plus, B, providers, facilities and physicians in
24 community practice.

25 Now the previous five questions, as I

1 mentioned earlier, are asked again as they pertain
2 to patients with no comorbidities having bariatric
3 surgery compared to nonsurgical medical
4 management.

5 DR. DAVIS: Thank you very much,
6 Dr. Brechner. Why don't we allow for a few
7 questions for Dr. Brechner if anybody has any.
8 Yes, Dr. Goodman.

9 DR. GOODMAN: Dr. Brechner, so as I
10 understand it, the reason that your literature
11 started in 2003 was simply to pick up from where
12 the Blue Cross Blue Shield tech assessment ended
13 in 2003.

14 DR. BRECHNER: Well, at the time that
15 we started, or we got notice that we were going to
16 do this, yes, it was late July, so we were looking
17 at tech assessments that were available, and after
18 that two of them popped up as being available, so
19 that one was written in 2003, in June, so what we
20 did was we figured that if they published it in
21 2003, they probably had data up to a month or two
22 before, so to play it safe we went back to April
23 2003 to search the general literature, but we went
24 back further for information on the elderly.

25 DR. GOODMAN: But your analysis is

1 confined to the lit search period that you
2 accessed?

3 DR. BRECHNER: Unless the TA covered
4 it.

5 DR. GOODMAN: Unless the TA covered it,
6 in which case you defaulted to the TA?

7 DR. BRECHNER: Well, I default to the
8 TA if I had no other information. If I had newer
9 information I used that instead.

10 DR. GOODMAN: And you mentioned the
11 NHLBI tech assessment.

12 DR. BRECHNER: Yeah.

13 DR. GOODMAN: And that was confined to
14 RCTs only collected by the Cochran collaboration,
15 correct?

16 DR. BRECHNER: I don't think so. I
17 think they had evidence grades of A, B, C and D in
18 their summary, and --

19 DR. GOODMAN: I believe they confined
20 it, but we can check. I just wanted to point out,
21 then, that the bodies of evidence considered among
22 the different assessments might not have the same
23 scope or depth.

24 DR. BRECHNER: Well, that's definitely
25 true.

1 DR. DAVIS: Yes, Dr. Weissberg.

2 DR. WEISSBERG: Ross, I appreciated
3 that summary. The critical distinction between
4 with or without comorbidities has been with us
5 since 1991 and has been made much of. Do you
6 think that that distinction is still as relevant
7 today, given that 40 to 90 percent of patients
8 when looked for will actually demonstrate
9 comorbidities?

10 DR. BRECHNER: That's a decision for
11 you guys to make based on the evidence today. I
12 just couldn't find any information on, in the
13 studies on persons that didn't have comorbidities
14 at surgery. I think that from when we reviewed
15 all the papers, and there were a lot of papers
16 that we reviewed, there were many papers that had,
17 I think, patients in the studies that were
18 operated that may not have had comorbidities. The
19 problem was that in just about every one of those
20 studies, they were concentrating on the resolution
21 of comorbidities and left out the opportunity, for
22 better words, of looking at those two groups
23 compared to each other.

24 DR. DAVIS: Yes, Mike.

25 DR. ABECAASSIS: Ross, I also want to

1 thank you for that review. So if you take
2 diabetes, for example, as one of the significant
3 comorbidities, there are many different ways to
4 define diabetes. A lot of people define diabetes
5 for the purposes of these studies as somebody
6 who's on either insulin or maybe an oral agent,
7 but that's not the way diabetes is defined I
8 believe by different societies and associations
9 that have looked carefully into the complications
10 of diabetes. So my question is, did you find any
11 uniformity in the papers that you did review with
12 respect to the definition of, for example,
13 diabetes?

14 DR. BRECHNER: No, I didn't find much
15 uniformity. A lot of the time it wasn't defined,
16 it was just listed as diabetes.

17 DR. DAVIS: Barbara.

18 DR. MCNEIL: The question of
19 comorbidities, I think is an important one, and I
20 was trying to get at where Jed was going, and I
21 was looking at the patient characteristics table
22 in Dr. Buchwald's meta-analysis. And if you look
23 at some of those data, for example, it says that
24 the data say that 40 percent of the patients had
25 hypercholesterolemia, so that presumably is a

1 standard definition, and that 25 percent had
2 impaired glucose tolerance, and that 60 percent
3 had degenerative joint disease, or 50 percent had
4 degenerative joint disease. And for example for
5 the degenerative joint disease, it looked to me as
6 if that might not correlate 100 percent with
7 diabetes or high cholesterol, so therefore you
8 could take the diabetes number and the cholesterol
9 number, and some big fraction of the joint disease
10 number because I wouldn't expect, as I said, there
11 to be any real correlation, and perhaps get some
12 estimate of the percentage of patients with
13 comorbidities going into the surgery. Does that
14 make sense? And if you did that, it comes out to
15 probably be pretty high.

16 DR. DAVIS: Dr. Sugerman?

17 DR. SUGERMAN: I'd like to make two
18 points at this stage. One is the Pope paper that
19 you mentioned that showed an increase in
20 comorbidity from 26 to 37 percent. I've talked to
21 Darby Pope, who's a resident at Dartmouth
22 Hitchcock, and he admitted the fact that those
23 data are extremely tenuous and weak. They were
24 based upon claims data and you know, many
25 discharge summaries won't have those data in it,

1 so it's a very poor look at comorbidities. It's a
2 good look at the number of operations performed,
3 but not a good look at comorbidities.

4 And just as an aside, when we looked at
5 our patients who had BMIs of 40 or greater, 3,000
6 patients in our series, 98.1 percent of them had
7 one or more comorbidities, and that excluded even
8 looking at quality of life. So most of these
9 patients, almost every patient who has a BMI of 40
10 or greater has a comorbidity.

11 DR. BRECHNER: Yes. You know, it was
12 hard for me to tell because a lot of the papers
13 reported X comorbidities without saying exactly
14 how many of their patients had one or more, they
15 concentrated over the broad range of doing that.
16 And the Pope paper, his methodology was good with
17 the sample that he had, and I agree that that
18 figure that he listed is questionable, but I
19 couldn't tell from the paper, there was no mention
20 of this in terms of limitations, and we're looking
21 for hard data.

22 DR. SUGERMAN: Again, the problem is
23 there has not been any motivation to look at the
24 patients who don't have any comorbidities, because
25 when we look at the criteria for surgery, it's a

1 BMI of 40 or greater.

2 DR. DAVIS: Thank you again, Dr.
3 Brechner, to you and your colleagues at CMS for
4 pulling together that very informative literature
5 review.

6 We're going to move on with the agenda
7 and begin with scheduled public comments. And
8 Dr. Walter Pories has worked with others in
9 arranging for this initial slate of presenters.
10 It is Dr. Wolfe who will begin, and we're going to
11 let this group of presenters speak until about
12 9:45 and then we're going to take a break and then
13 we'll continue on with scheduled public comments.
14 Dr. Wolfe.

15 DR. WOLFE: Thank you. My name is
16 Bruce Wolfe, I am professor emeritus of surgery at
17 UC Davis and practice bariatric surgery in
18 Sacramento. I am co-chair of the NIH bariatric
19 surgery consortium which is known as LABS. I have
20 received financial support both for research and
21 honoraria in the past from U.S. Surgical
22 Corporation and Ethicon Endosurgery. My present
23 research is funded by NIH. My expenses for travel
24 to today's conference will be reimbursed by the
25 American Society for Bariatric Surgery, known as

1 the ASBS. I serve on the medical review committee
2 of Blue Shield of California.

3 Dr. Pories has organized a group
4 presentation, a decision was made to consolidate
5 those talks, so not all of the listed speakers
6 will in fact speak.

7 I would like to begin by recognizing
8 the contributions of Secretary Thompson in
9 recognizing the problem of obesity and addressing
10 it. I would like to thank Chairperson Davis and
11 the members of the panel for the opportunity to
12 present, and particularly thank the executive
13 secretary Miss Long for her patience and
14 assistance in helping us prepare our presentation.

15 Dr. Brechner has already addressed the
16 increased demand for bariatric surgery, the
17 obesity epidemic. Epidemiologic research
18 demonstrates that obesity is a life threatening
19 disease and surgery is the only effective
20 treatment which is presently available. These
21 factors have combined to create this increased
22 demand for bariatric surgery.

23 This slide from the Swedish Obese
24 Subjects Study has already been shown. I focus on
25 the control patients who did not undergo surgery

1 but underwent the best nonsurgical treatment
2 available. We see the characteristic transient
3 weight loss with nonsurgical treatment followed by
4 a regain of the weight, and in fact in six to
5 eight years a net gain of weight among those
6 patients. It is this observation that is
7 fundamentally the reason that in practice it is
8 not possible to recruit or retain patients in
9 nonsurgical arms comparing nonsurgical with
10 surgical therapy.

11 We recognize as researchers in the
12 field the classification scheme for the quality of
13 the data and that we do not have randomized
14 control trials or Level I data regarding surgical
15 versus nonsurgical controls to present today. We
16 will present data that represent the distillation
17 of three years of initiatives by the surgical
18 community and others, including the recent ASBS
19 consensus conference, the AHRQ-sponsored
20 technology assessment, and other technology
21 assessments as we have heard, as well as the
22 NIH/NIDDK-funded consortium on surgery or LABS.

23 Today we will be presenting the
24 aggregated results of many observational studies
25 that together represent the preponderance of the

1 evidence to address the five questions that have
2 been posed to the panel. The basic operations
3 that are in use have already been discussed as
4 well; they are restrictive and bypass operations.
5 It's beyond the scope of this conference to get
6 into the precise mechanism by which these
7 operations accomplish weight loss.

8 First, the gastric bypass. Several
9 authors have reported series with ten or more
10 years of follow-up. Dr. Pories reported on 600
11 patients with 97 percent follow-up, a weight loss
12 at two years of 70 percent of excess body weight,
13 58 percent at five years, and 55 percent at ten
14 years. We've seen data on postoperative
15 complications, they range from 5 to 20 percent.
16 Long-term complications consist of ventral hernia
17 in 10 to 30 percent, a problem that is essentially
18 eliminated by the laparoscopic approach to gastric
19 bypass. Late nutritional deficiencies do occur
20 but are preventable and treatable by appropriate
21 supplementation.

22 The open versus laparoscopic approach
23 is of interest inasmuch as the great majority of
24 bariatric operations are done in this country by
25 laparoscopy at this time. The benefits of

1 laparoscopy for all procedures include diminished
2 injury response leading to diminished
3 postoperative pain. That is thought to be
4 fundamental in reducing the disturbance of
5 pulmonary function that abdominal surgery produces
6 and lowering the complication rate of pulmonary
7 complications. There's diminished stimulation of
8 hypercoagulability of blood, there's more rapid
9 recovery, and most importantly, there's diminished
10 wound complications.

11 This is some of the data from a
12 prospective randomized trial conducted by Winn and
13 myself at UC Davis that showed in laparoscopic
14 versus open gastric bypass less use of intensive
15 care unit, shorter hospital stay, more rapid
16 return to activity, and other benefits as I
17 indicated.

18 This is a summary slide with several
19 reports on laparoscopic gastric bypass outcomes
20 showing weight loss in the range of 70 to 80
21 percent in keeping with the data for open gastric
22 bypass. Our data which has been presented but not
23 published at 3.5 years in the randomized trial
24 shows that the weight loss is identical among the
25 two groups. It is therefore reasonable to pool

1 together the outcome results regarding weight loss
2 for laparoscopic and open gastric bypass.

3 Complications of Roux-en-Y gastric
4 bypass do occur. In the randomized trials the
5 incidents were similar although the specific
6 complications were somewhat different. Mortality
7 rates are in this column to the right that have
8 been reported in range from 0 to 3 percent.

9 The laparoscopic adjustable gastric
10 band has been described by Dr. Brechner as well.
11 There are, the band has been available in the
12 United States for just three years and so we're
13 dependent on international data for follow-up
14 beyond that. There are three trials that have
15 data out six to eight years demonstrating excess
16 body weight loss in the range of 50 to 59 percent.

17 As has already been mentioned, the
18 complication rate for laparoscopic adjustable
19 gastric banding is not zero, but most authors
20 report no mortality, the range is up to 1.2
21 percent in these series, and other complications
22 that are mechanical related to the band itself do
23 occur and are generally manageable.

24 This is still one more technology
25 assessment done by the Australian government in

1 which they performed a similar technology
2 assessment as what we've heard about already
3 today. And what they found was that the mortality
4 for laparoscopic adjustable gastric band was very
5 low, at .05 percent, morbidity of 11 percent, as
6 opposed to Roux-en-Y gastric bypass, the mortality
7 of 0.5 percent and higher morbidity. The vertical
8 banded gastroplasty is an operation that is used
9 much less frequently in the United States at this
10 time and so we won't be focusing on that
11 operation.

12 The weight loss they showed was that at
13 two years the Roux-en-Y gastric bypass has
14 superior weight loss to the banding, but at four
15 years both operations result in significant weight
16 losses, the weight losses are closer together at
17 four years than at two.

18 The diagram for biliopancreatic
19 diversion with or without duodenal switch has also
20 been shown this morning. The results are seen
21 here. A single surgeon, Dr. Scopinaro, who
22 basically devised the procedure, a very large
23 series with excellent results, 78 percent excess
24 body weight loss at 12 years and acceptably low
25 complications. 3.2 percent stomal ulcers with H2

1 blockers, 12 percent without, a certain amount of
2 protein malnutrition, 7 percent, concern regarding
3 bone demineralization as malabsorptive procedures
4 may lead to net calcium loss.

5 The modification of the duodenal switch
6 in which the anastomosis is post-pyloric shows a
7 similar weight loss at 80 percent at two years,
8 and also acceptably low complication rates. Of
9 interest, the duodenal switch appears to avoid the
10 problem of stomal ulcers for the most part,
11 malnutrition complications do occur following
12 malabsorptive procedures.

13 Both of these procedures, particularly
14 the duodenal switch has been reported as having
15 been accomplished by laparoscopy. There are five
16 such cohorts, the data is very similar with regard
17 to the complications and outcomes. Length of stay
18 is shortened by the laparoscopic approach.

19 The impact of bariatric surgery on
20 comorbidity is of interest as we have also heard.
21 This and following slides are adopted from the
22 meta-analysis published by Dr. Buchwald very
23 recently in JAMA. This meta-analysis includes
24 several thousand, approximately 7,000 cases, and
25 is obviously very current. What we see is that

1 weight loss is basically quite good for all of the
2 procedures. The relatively short follow-up for
3 the banding procedures in the meta-analysis as a
4 result of the shorter time the band has been
5 available may disadvantage the band in these
6 results. Otherwise, the results are quite similar
7 with regard to the maintenance of weight loss.

8 Perhaps most impressive is the
9 resolution of diabetes by surgical weight loss.
10 While the exact definition of diabetes is not
11 indicated in those papers, most of us use the
12 standard definition, which is blood sugar fasting
13 less than 126. And resolution of the diabetes is
14 reported in 80 to 90-plus percent of the patients
15 in these series. Again, the shorter follow-up for
16 band is perhaps a disadvantage with the
17 methodology used in this study.

18 Similar improvement with hyperlipidemia
19 in excess of 80 percent, hypertension 60 to 70
20 percent as we saw, not quite as impressive as the
21 data for diabetes and dyslipidemia. The
22 resolution of obstructive sleep apnea syndrome,
23 which is being found to prevail in this patient
24 population at a much greater frequency than has
25 been recognized in the past, some say greater than

1 50 percent if you study the people in detail,
2 resolution occurring in 80 or more percent for all
3 of the procedures.

4 Finally, fatty liver, steatohepatitis
5 is an increasingly recognized problem in patients
6 with morbid obesity, it's predicted by some to
7 replace hepatitis C as the most common indication
8 for liver transplant in the near future, and data
9 of Kral showing that it does respond to weight
10 loss induced by surgery.

11 Other comorbidities, of which there are
12 numerous, are similarly improved by weight loss.
13 The common theme is the response of the
14 comorbidities if they are indeed obesity-related
15 or caused comorbidities would be expected to
16 resolve with weight loss and indeed that is the
17 pattern we see. It doesn't matter which operation
18 it is, if the weight is lost, then these
19 comorbidities if they are properly attributed to
20 the obesity, do indeed improve or resolve.

21 Thank you for your attention.

22 DR. FLUM: Thanks to the committee for
23 giving me the opportunity to speak today. My name
24 is David Flum, I'm a gastrointestinal laparoscopic
25 surgeon at the University of Washington. I'm also

1 an outcomes researcher with formal training in
2 surgical epidemiology and technology assessment.

3 We've divided this presentation today
4 to give you separate perspectives. This
5 perspective is from a health services broader
6 perspective, if you will, one that deals with some
7 of the issues of survival, both short and long
8 term, and health utilization outcomes that are
9 relevant in trying to make decisions and
10 assessments about bariatric surgery.

11 By way of housekeeping, my present
12 funding includes NIH funding from NIDDK. I'm the
13 principal investigator in the consortium for
14 bariatric surgical research and in the past I've
15 received funding from INAMED for a small research
16 project. My travel expenses today were paid for
17 by the Society for Bariatric Surgery and as I
18 said, I'm pleased to be here.

19 Obviously when we're dealing with the
20 issue of survival and long-term survival with
21 bariatric surgery, the issue of what is the
22 alternative comes to bear. We know that this year
23 approximately 400,000 lives will be lost due to
24 obesity alone. Intuitively as clinicians, we know
25 that as you reduce comorbid conditions such as

1 diabetes, perhaps the banner comorbid condition,
2 we expect long-term survival to be achieved, since
3 we know that diabetes is linked to a worsened
4 survival.

5 But this also assumes a low rate of
6 perioperative death related to the procedure of
7 course, and you have heard today many case series
8 and voluntary databases, the preponderance of
9 which speak to very low risk of mortality with
10 bariatric surgery. To view this as a skeptic,
11 someone who really critically evaluates outcomes
12 in the surgical community, our group tried to look
13 at the population at large to assess the variable
14 mortality in the rear world, if you will. We
15 looked at over 60,000 patients in the state of
16 Washington who had been hospitalized with
17 diagnostic codes related to obesity and morbid
18 obesity, of which approximately 3,000 underwent a
19 gastric bypass operation.

20 As noted earlier, we identified a 1
21 percent risk of in-hospital mortality,
22 considerably higher than others have noted, and
23 approximately a 2 percent risk of 30-day
24 mortality. Now, although those numbers are
25 considered alarming by some, or certainly higher

1 than what you've heard before, when we tried to
2 understand, if you will, what was underlying that
3 higher rate of morbidity and mortality, strike
4 that, mortality, we found that surgical
5 inexperience was really linked to it more than
6 anything else, and if the surgeon had done less
7 than 20 procedures, there was clearly almost a
8 five times higher risk of death. And when you
9 looked at those more experienced surgeons later on
10 in their curve, if you will, the mortality rates
11 that you've heard today from the case series will
12 ring true even in the community at large. That's
13 the caveat that I would offer.

14 And I tried to contextualize that
15 mortality rate, you know, that 1 percent
16 in-hospital mortality rate. This is unpublished
17 data from a MedPAR analysis that's recently been
18 performed looking at a couple of thousand patients
19 who had bariatric surgery for obesity with gastric
20 bypass DRG, showing a 1 percent mortality rate in
21 hospital, almost identical to the state of
22 Washington's data. And by way of context, total
23 joint replacement was listed as 1 percent, with
24 bypass at three percent. That's important because
25 joint replacement, essentially an elective

1 operation often due to the ravages of obesity, but
2 it helps to put in context the mortality data I
3 have shown.

4 Now this is the short-term data.
5 Obviously when you're considering survival, it's
6 the balance of long and short term, and although
7 we feel most confident as a surgical community
8 talking about diabetes as an important comorbidity
9 that's reduced, and we point to lots of evidence
10 that shows the other comorbid conditions improve,
11 survival has been the one that we have been, it
12 has been the hardest to demonstrate for lots of
13 obvious reasons. We need long periods of time for
14 follow-up and appropriate cohorts.

15 There have been three studies that help
16 to inform this, one by Ken McDonald which
17 demonstrated that a 28 percent mortality rate in
18 patients on the waiting list and a 9 percent
19 mortality rate in patients who had the operation
20 for gastric bypass in a large cohort.

21 There is this study in Washington state
22 that shows, by our group, that shows a crossing of
23 the lines at about one year. Patients who had a
24 gastric bypass seemed to do better than those who
25 did not have a gastric bypass outwards of 10 and

1 15 years. And the data that supports that at 15
2 years, 16 percent of the people in the
3 nonoperative cohort had died, compared to 11.8
4 percent of the people in the operated cohort.
5 This was particularly emphasized in the
6 younger-aged group and after one year as
7 mentioned, there was a third lower risk of death
8 in the operated cohort than nonoperative.

9 The last bit of evidence that supports
10 this comes out of Canada, which details the cohort
11 of patients performed at McGill, and a control if
12 you will of patients derived from administrative
13 data in Quebec. They looked at a thousand
14 patients in the operative group and five to one
15 matching, if you will, for the control. They
16 found a 6 percent rate of aggregate mortality in
17 the nonoperative group and a .68 percent rate of
18 mortality in the operative group, a relative risk
19 of .11 or a risk reduction of 89 percent in that
20 cohort. They also found significant drop-offs in
21 new-incident cases of cancer, infectious disease,
22 musculoskeletal disease, all of these conditions
23 an significant drop-offs in utilization.

24 We have some time restrictions today
25 that will probably limit our exploration of the

1 issue of cost and health care utilization, but
2 this study in particular was helpful in
3 demonstrating that the costs of bariatric surgery
4 are amortized over about three-and-a-half years,
5 and this is reinforced by lots of work that we
6 have performed and I would be glad to comment on
7 that later. Once again, thank you for the
8 opportunity to present today and I look forward to
9 your questions.

10 DR. WADDEN: Good morning. I'm Tom
11 Wadden, professor of psychology at the University
12 of Pennsylvania School of Medicine. Thank you
13 for the opportunity to speak today on behalf of
14 the North American Association for the Study of
15 Obesity, of which I'm vice president, and also on
16 behalf of the American Society for Bariatric
17 Surgery. In terms of disclosure, I received a
18 one-time honorarium from Ethicon Endosurgery for
19 participating in a meeting, and I'm paying my own
20 travel expenses today.

21 I originally had ten slides in my
22 presentation which Dr. Pories has reduced to five
23 in the interest of time, surgeons like to cut, so
24 thank you, Walter.

25 (Laughter.)

1 DR. WADDEN: So I will be making some
2 remarks that are not supported by slides. I think
3 it's important that we talk about the adverse
4 physical effects of extreme obesity today and of
5 the benefits resulting from weight reduction. I
6 want to talk some about the adverse psychosocial
7 consequences of extreme obesity, which include
8 depression, eating disorders, impaired quality of
9 life. In addition, persons with extreme obesity
10 suffer marked prejudice and discrimination that
11 truly can scar their lives.

12 A recent population study by Anjac and
13 colleagues showed that persons with a BMI of 40 or
14 greater had nearly five times the rate of major
15 depression as persons of average weight. You can
16 see that persons with a BMI of 35 or greater had
17 nearly double the rate of major depression in the
18 past year. Major depression is a frightening
19 condition in which you feel like your life is
20 worthless and you have little hope of getting
21 better.

22 In addition, approximately 25 percent
23 of bariatric surgery patients suffer from binge
24 eating disorder. This condition is characterized
25 by the consumption of large amounts of food in a

1 brief period of time and patients feel out of
2 control of their eating and it feels compulsive,
3 and again, people are very distressed by this
4 condition, this is not pleasurable eating.

5 Even if they do not experience frank
6 depression or eating disorders, a significant
7 majority of patients with extreme obesity report
8 impairments in health-related quality of life.
9 The SF-36 is a scale that measures quality of life
10 in eight different domains with higher scores
11 going up to 100 indicating better functioning. In
12 this slide, scores of the normal population are
13 shown in the yellow part of the bar, so the higher
14 the score the better the functioning, whereas the
15 bariatric surgery candidates prior to surgery are
16 shown in the green color. So you can see that
17 surgery candidates report marked impairment
18 starting on the left, in physical functioning.
19 They report impairments in their role performance
20 at work and in recreational activities. They
21 report reduced vitality, and an important thing to
22 note in the third column there is that they report
23 bodily pain. This is a physically distressing
24 condition.

25 I want to discuss improvements in

1 psychosocial function that occur with weight loss
2 following surgery. It's important to note that
3 research in this area is limited, there are no
4 randomized controlled trials as others have
5 discussed previously. Most studies have been
6 small and few of the patients have been 65 years
7 or older. However, there are some strengths,
8 including the Swedish Obese Subject Study that
9 you've heard about, and the use of well validated
10 measures. Depression clearly improves following
11 weight reduction with bariatric surgery, as shown
12 by the SOS study. It's also shown in a recent
13 study by Dr. John Dixon, who found that reductions
14 in depression were maintained at four years. You
15 also see that there are marked improvements in
16 quality of life; now the yellow shows the
17 performance of patients after bariatric surgery,
18 and they now meet the values of normal samples.

19 Finally, it's hard to quantify the
20 emotional hardship that patients with extreme
21 obesity experience from the prejudice and
22 discrimination directed at them. It is perhaps
23 best captured by this slide. This is a study
24 showing that patients who have lost 100 pounds,
25 kept it off for three years or more, reported that

1 they would prefer to be normal weight and to have
2 a major disability, including blindness or limb
3 amputation, than to return to morbid obesity
4 again.

5 So this brief review has shown that
6 extreme obesity is associated with significant
7 psychiatric comorbidity and suffering and it is
8 dramatically relieved by weight loss following
9 bariatric surgery. Thank you.

10 DR. STILES: Good morning. My name is
11 Sasha Stiles, I am a medical physician and I also
12 have an M.P.H. in administration and planning.
13 Can you hear me now? I would like to say as a
14 disclosure that I am an employee of Kaiser
15 Permanente and as such I speak to all Kaiser
16 employees and also the state offices in California
17 because of my role. I am the medical director for
18 bariatric surgery for Kaiser South San Francisco
19 and Northern California. I'm also the national
20 clinical lead for bariatric surgery for the Kaiser
21 Permanente Care Management Institute.

22 I'm a primary care doctor and I've been
23 one for over 25 years. I have seen many of my
24 patients die from their severe obesity over this
25 time. Now with bariatric surgery, they have a

1 chance to survive but also to thrive. I know of
2 no other intervention which can so profoundly
3 ameliorate or resolve the medical, social and
4 psychological comorbidities of severe obesity.
5 Patients seeking or referred for bariatric surgery
6 that I see routinely have undergone five to seven,
7 and often 15 to 20 prior attempts at other weight
8 loss and dietary treatments.

9 After surgery for colon cancer, my
10 patients receive radiation, chemotherapy, and
11 long-term follow-up. If they have a recurrence,
12 we blame the disease. If a severe obese patient
13 begins to gain back their weight, we blame the
14 patient's lack of will power or we blame the
15 surgery, forgetting that it is really the disease
16 of severe obesity which we are trying to treat.

17 Research points to conditions which
18 must be evaluated preoperatively, high BMI,
19 pulmonary function tests, EKG abnormality, sleep
20 apnea, hypertension. Preoperative weight loss has
21 now been even shown to be predictive of long-term
22 success. At Kaiser Permanente I personally
23 evaluate all patients and rigorously strive to
24 improve or stabilize all their chronic diseases
25 before surgery. We have weekly education,

1 nutrition and exercise programs. We have
2 psychological assessments and treatment options.
3 We have case management for special conditions and
4 weekly support groups by a trained facilitator.

5 The SOS study found a 32 percent
6 decrease, 32-fold decrease in diabetes in their
7 surgical group versus control. We all know
8 Pories' landmark work. I can tell you that my
9 diabetic patients are the absolutely most
10 grateful. No longer do they have to fear a life
11 of amputations, dialysis, heart attacks and
12 blindness. Preoperatively, my sleep apnea
13 patients are predictive of increased sick leave,
14 divorce, impaired work performance and ill health.
15 Buchwald's meta-analysis shows 85 percent resolve
16 after surgery, and I find this too. The more
17 weight you lose, the less pain in your weight
18 bearing joints. The most common wish, and this is
19 really true, that my patients tell me and that
20 they wish for after surgery is to run around after
21 their grandchildren and you know what, they really
22 do.

23 Pseudotumor cerebri resolves within
24 four months, relief of massive headaches, and
25 spinal taps. If any of you have seen this

1 disease, it really is quite remarkable what we can
2 do. GERD and asthma vastly improve, and inhalers
3 are frequently thrown away by six months.
4 Venostasis resolves; my teachers can now stand up
5 in front of their class instead of sitting behind
6 their desks with their Una boots, and they're free
7 of pain and swelling. Urinary incontinence vastly
8 improves. Do you know how great it is for a woman
9 not to concentrate on where all the bathrooms are
10 in her life?

11 Also, sick leave by two years after
12 surgery has been decreased by 10 to 18 percent. I
13 see my patients going back to work. These are
14 sometimes patients who have been off work for 10,
15 15 and more years. At Kaiser Permanente we have
16 detailed follow-up by multiple providers in person
17 and over the phone over the first six months.
18 Thereafter I run regular long-term follow-up
19 groups where several patients, myself and the
20 staff develop treatment protocols for the rest of
21 their life. We do this every six months like
22 clock work for all our patients. All patients are
23 also evaluated for their long-term care issues by
24 the appropriate member of our team, dietitian,
25 psychologist, bariatric surgeon or myself. And we

1 also have postoperative support group classes
2 which are educational classes which are held
3 weekly, where we have actually 60 to 80 patients
4 at least a week, and more.

5 Finally, there is just no other model
6 out there which can hold a candle to the
7 possibility that this surgery gives my patients.
8 As a primary care doctor, I also feel strongly
9 that the best surgical outcomes are gained with a
10 pre-op and long-term postoperative
11 multidisciplinary chronic disease management
12 approach which is what we do at Kaiser Permanente
13 on many diseases, and I can tell you it works. It
14 promises to maximize the benefits of this
15 incredible surgery. This surgery offers hope when
16 there really was none to my patients. Let's work
17 together and make this work. Thank you very much.

18 COL. STRADDIFF: Good morning. My name
19 is Robert Straddiff and I'm a retired U.S. Army
20 colonel with 32 years service. I was both a fixed
21 wing and helicopter pilot for the majority of
22 those years and put in two combat aviation tours
23 in Vietnam. My military career progressed and as
24 it progressed, my duty assignments gradually
25 became staff jobs, but I always maintained my

1 flight status. I only mention these things to
2 highlight the fact that I was subject to annual
3 flight physicals and the strict weight standards
4 required to remain on flight status.

5 After my retirement I accepted a
6 civilian position at Fort Lee, Virginia. While
7 there, I continued my normal PT program of a
8 three-to-five mile run four or five days a week.
9 I retired from my civilian job in '92 and a few
10 months later my problems began. On one of my runs
11 I experienced severe pains in my left knee.
12 X-rays revealed I had bone on bone contact. I had
13 two choice, a try at physical rehabilitation or a
14 knee replacement. I opted for rehab and all went
15 well until the summer of '94 when I blew out my
16 right knee and I went to the rehab group once
17 again.

18 But the weight gain was dramatic and I
19 didn't seem to be able to control it by diet
20 alone. By this time both knees were too painful
21 for any comprehensive exercise program, so the
22 pounds kept mounting up. Along with the weight
23 gain came the inability to get a good night's
24 sleep. I was now experiencing sleep apnea and
25 started to sleep sitting up in an easy chair in my

1 bedroom. I slept this way for months, when I
2 noticed that there was moisture around the calf
3 areas of both legs. I was diagnosed with and
4 treated for venostasis dermatitis.

5 It was during this time that I happened
6 to read an article in the Richmond Time-Dispatch
7 concerning the gastric bypass work that
8 Dr. Sugerman was doing at the Medical College of
9 Virginia. I expressed a desire to look into it
10 and my doctor encouraged me to see Dr. Sugerman
11 for more details. After my initial consultation
12 and evaluation, I decided to have the surgery. I
13 knew that if I didn't, I wouldn't survive. By
14 this time my weight was 360 pounds and I had begun
15 to have angina problems. I was desperate, I could
16 barely walk, I was now using two canes, and I was
17 in constant pain in my knee joints. I found
18 myself a near recluse.

19 I knew I had to do something and
20 quickly, so at the age of 69 I had Roux-en-Y
21 bypass surgery done in February 2002. The first
22 month was the worse, not much pain, and the pureed
23 foods were not much to be recommended, but the
24 change was dramatic. In six months I had lost 80
25 pounds, the ulcers were gone, the apnea had

1 gradually disappeared and I was back in my bed
2 getting a good night's sleep. Almost as rewarding
3 as the weight loss was my ability to get back
4 exercising and this time it was a swimming
5 program.

6 In October of 2002 I had a complete
7 knee replacement on my left knee, continued
8 swimming, and by Christmas of 2002 I had lost
9 another 60 pounds. Since my bypass surgery I have
10 gone from 360 to 160, or 65, for a total of a
11 195-pound weight loss. Another follow-up from the
12 weight loss is that right knee replacement is now
13 unnecessary, I can get along just fine, and even
14 take an occasional two-mile walk.

15 That concludes my remarks. Thank you
16 very much.

17 MS. TANNER: Good morning. My name is
18 Stella Tanner, I'm 68 years old, and I had
19 laparoscopic gastric bypass surgery two years ago
20 at age 66, and I have lost 75 pounds.

21 The last few years before my surgery
22 were absolutely horrible. I dreaded waking up
23 each morning to another day of excruciating pain
24 and total exhaustion. I had sleep apnea, I used a
25 Bi-PAP machine at night. I was taking increasing

1 amounts of blood pressure medication. I was
2 plagued with incontinence that required constant
3 attention, infections and discomfort. I suffered
4 from migraine headaches and my doctor was
5 concerned with my increasing blood sugar level.

6 My surgery was not cosmetic, but it was
7 a desperate attempt to enable me to once again
8 take care of my family and my home, and I have
9 been rewarded with much more than that. This
10 operation absolutely saved my life. In the past
11 18 months my husband and I have traveled to
12 Alaska, we have been to the beach several times,
13 been to more football and baseball games than you
14 can possibly imagine, golfed for two weeks all
15 over California, and recently spent two weeks in
16 Italy. Instead of being an invalid in
17 excruciating pain, my life is absolutely
18 wonderful, and it's all due to this surgery.

19 Please continue this surgery for
20 Medicare patients. I am extremely grateful that I
21 was provided with this coverage and I will spend
22 the rest of my life trying to repay the world for
23 my good fortune. Other senior citizens deserve
24 this same opportunity. Thank you.

25 DR. PORIES: Mr. Chairman, members of

1 the panel, my name is Walter Pories. I am a
2 bariatric surgeon, a professor of surgery and
3 biochemistry at East Carolina University, a
4 principal investigator and co-investigator for
5 several NIH grants, and the president of the
6 Surgical Review Corporation, which paid for my
7 expenses to come here. I've also lectured for
8 Johnson & Johnson and the Tyco Corporation.

9 Before I start, I want to thank Miss
10 Long for her mothering us through this process,
11 we're very grateful.

12 My assignment is to address the fifth
13 question, can we generalize these excellent
14 outcomes to community practice and the Medicare
15 population? Or to phrase it more precisely in
16 terms of the needs of our society, can we provide
17 excellent bariatric surgery to the Medicare
18 population? To achieve this aim, we would need to
19 meet a very difficult and rigorous challenge, to
20 follow the lead of industry in delivering a
21 consistent and high quality surgical product. A
22 very difficult goal, some might say unattainable.
23 To reach it, we would need to standardize our
24 operations, standardize patient care paths,
25 monitor the providers, rigorously collect short

1 and long-term data, and verify that information by
2 site visits.

3 Well, surgeons want good results at
4 least as much as you do, and with a remarkable
5 move, the membership of the ASBS voted to address
6 quality clinical outcomes by using evidence-based
7 medicine in establishing standards for bariatric
8 surgery. The ASBS addressed this issue by
9 supporting the founding of an independent
10 organization, the Surgical Review Corporation to
11 pursue this goal and to designate those who meet
12 these tough standards, and they are tough, as the
13 ASBS centers of excellence.

14 The Surgical Review Corporation is a
15 totally independent nonprofit organization in
16 which the board of governors include the
17 stakeholders in bariatric surgery, including the
18 CEO of Blue Cross Blue Shield, of a Blue Cross
19 Blue Shield, a CEO of a malpractice carrier, two
20 former presidents of the American College of
21 Surgeons, and a consumer. Most telling, only
22 three of the 12 members are bariatric surgeons.
23 Let me emphasize our independence. There are no
24 relationships between the SRC and the NIH or the
25 American College of Surgeons, or industry.

1 As the president of the Surgical Review
2 Corporation, I report to you that we are well
3 underway. Over 250 centers have already applied
4 for provisional status with contracts that they
5 will follow these stringent ground rules. We
6 expect to name our first centers by June of next
7 year. This is a remarkable beginning. We are as
8 intent on answering the fifth question as you are.

9 The surgical community will consider as
10 favorable any initiative by CMS that would help
11 advance our knowledge of the impact of bariatric
12 surgery based on practical evidence gained in
13 practice in the Medicare population. The SRC
14 would be more than pleased to facilitate such an
15 activity. Thank you.

16 DR. FLUM: This is David Flum again. I
17 was asked to bat cleanup, if you will, to help
18 frame the discussion that we've had so far within
19 the context of your evaluative questions, the two
20 pages of evaluative questions you have regarding
21 obesity patients with comorbidities and obesity
22 patients without comorbidities. Once again, it's
23 been a privilege to speak with you today and also
24 let you know that the messages that Bruce Wolfe
25 and I have put forward today really represent more

1 than 30 to 50 surgeons that have had input into
2 this discussion today. It's hard to speak for all
3 the surgeons, but collectively we're trying to
4 demonstrate our sense of the literature.

5 You know, as a critic of the surgical
6 and scientific literature what you're seeing today
7 is an overwhelming number of observational
8 studies. Your second question deals with how
9 confident can you be in the validity of the
10 scientific data to support all the questions
11 listed there, and the validity brings up the
12 question of what type of validity. Obviously this
13 is not type one data, it would be unethical in
14 fact to randomize patients to an intervention that
15 had a one to two percent mortality rate and a
16 diet, and it's simply not feasible either.

17 But there is another type of validity
18 which is face validity that we're all familiar
19 with. Face validity speaks to the preponderance
20 of evidence and we now have 15 studies that
21 demonstrate long-term weight loss being sustained
22 beyond five, upwards to ten years, and at least
23 five studies that demonstrated out beyond 15
24 years. We have three studies, as I mentioned,
25 that looked at long-term survival, all of them

1 with agreeably flawed comparator groups but speak
2 to a general sense of face validity. We have lots
3 of evidence that details 30-day mortality with
4 really good, a preponderance of evidence speaking
5 to a general sense of at least reported outcomes
6 for 30-day mortality. And we know the JAMA
7 article related to comorbidities speaks to
8 preponderance of evidence, the 18,000 patients
9 pooled from multiple studies that speak to face
10 validity.

11 So in the absence of that gold standard
12 data, what we can say is that the surgical
13 community as advocates for our patients, as people
14 who see the clinical outcomes, and as people who
15 balance research that's out there, limited as it
16 may be, we think the preponderance of evidence
17 supports the validity and a high level of
18 confidence in the validity of the scientific data
19 for all those points that I just mentioned.

20 It should also be mentioned that our
21 colleagues in internal medicine and preventative
22 health have nicely looked at the other side of
23 this, which is what are the nonsurgical
24 approaches, and have really demonstrated quite
25 nicely, Kathleen McTighe's article for the U.S.

1 Preventative Health Task Force really comes to
2 mind, demonstrating the futility of long-term
3 solutions that are nonsurgical and the lack of
4 data beyond one to two years for the vast majority
5 of nonsurgical alternatives. That's question
6 number one for you.

7 Question number four speaks to all the
8 different types of procedures that we are and how
9 confident are we as a surgical community that the
10 procedures will have a significantly important
11 clinically important net health benefit. Clearly
12 we've demonstrated and reported multiple
13 observational studies. The preponderance of
14 evidence once again speaks to support for these
15 procedures.

16 And all the studies have an issue of
17 publication bias and that has to be dealt with
18 when considering face validity. We're not seeing
19 the series of less than good outcomes, I suspect,
20 but face validity is based on what it is, and
21 there are clinical outcomes and then there's
22 observational studies, and we believe this is the
23 best evidence there is to date.

24 The last question has to do with the
25 issue of how generalizable is the data that you've

1 heard today to the Medicare population,
2 specifically those greater than 65, and to
3 providers in community practice. To the first
4 point about those greater than 65, one thing we
5 know about outcomes in bariatric surgery is that
6 age seems to have a direct, an independent effect;
7 the older you are, the less performance or the
8 worse outcomes you have.

9 Clearly, you've heard passionate
10 responses from patients who have had the surgery
11 who are older, and those are very important
12 messages to hear, but we know that there is an age
13 relationship to adverse outcome, and simply there
14 is a limitation in the data that's available on
15 this topic, although certain cases series even by
16 Dr. Sugerman have shown very low or no mortality
17 in certain case series in certain hands.

18 We can't speak to the more
19 generalizable issue of the population greater than
20 65, but I think it's important to recognize that
21 in the Medicare population that's covered right
22 now, more than 80 to 90 percent of the patients
23 who are covered are under the age of 65. This is
24 the Medicare disabled groups, so clearly the
25 critical emphasis is in that population.

1 To the last point about the
2 generalizability of the data we've presented today
3 to the community at large, in our work in
4 Washington state we've had a hint towards that,
5 how generalizable is this data, and we really
6 won't know until we have more population level
7 evaluations of this issues, and the centers of
8 excellence may be a wonderful way to get that sort
9 of population level assessment.

10 The last issue is the whole second
11 page, of how to assess obesity patients with no
12 comorbid conditions. Dr. Sugerman has helped to
13 highlight this point. We don't have a lot of
14 information on this topic for two reasons. One,
15 because to date, surgeons can't operate on
16 patients with BMI of 35 to 40 without comorbid
17 conditions, there will be no data available
18 because we can't operate on this population, it's
19 not a covered benefit for the most part.

20 Of patient greater than on 40, you
21 would be hard pressed to find surgeons or
22 physicians in general who take care of patients
23 with a BMI greater than 40 that would say that
24 they have, or that they don't have any comorbid
25 conditions. If you scratch under the surface just

1 a little bit, you'll find comorbid conditions that
2 are not well reported or not obviously listed in
3 administrative databases, or people just not
4 asking about things like urinary incontinence and
5 sexual dysfunction and gastroesophageal reflux.

6 So I thank the committee and look
7 forward to any of your questions, but that's the
8 way we wanted to contextualize this information.

9 DR. DAVIS: Thank you very much. We're
10 going to take a break in a moment, but I'm not
11 sure that all the presenters from the past hour or
12 so made a conflict of interest disclosure. If
13 anybody missed one and failed to indicate whether
14 or not they have a financial conflict of interest
15 and who funded their travel to this meeting,
16 perhaps you could do that now and we could get
17 that into the record, or the transcript, and then
18 we could take a break and then continue on with
19 the presenters.

20 COL. STRADDIFF: I am Colonel
21 Straddiff. I have no conflicts of interest.

22 DR. DAVIS: And your funding to this
23 meeting was provided by?

24 COL. STRADDIFF: Myself.

25 MS. TANNER: I'm Stella Tanner. I do

1 not have any conflicts of interest and my husband
2 is paying for my stay.

3 DR. STILES: I'm Sasha Stiles and I
4 forgot to say, I'm sorry, the ASBS paid for my
5 stay and coming here.

6 DR. DAVIS: And any financial conflicts
7 of interest?

8 DR. STILES: No, sir, I just work for
9 Kaiser Permanente.

10 DR. DAVIS: Thank you very much. We'll
11 take a 15-minute break and then continue on with
12 the public comments.

13 (Recess.)

14 DR. DAVIS: We have a series of
15 presenters who will continue for the next, oh,
16 hour or so. And hopefully before the lunch break
17 we will have an opportunity for questions from the
18 members of the committee. Mary Lee Watts.

19 MS. WATTS: Good morning. My name is
20 Mary Lee Watts.

21 DR. DAVIS: While we're working on the
22 microphone, I just want to remind the presenters
23 for this next segment to, again, make their
24 conflict of interest disclosure and indicate how
25 you were funded to the meeting. Thank you.

1 MS. WATTS: My name is Mary Lee Watts.
2 I have a masters in public health and I am a
3 registered dietitian. I am currently serving as
4 manager for legislative and political affairs at
5 the American Dietetic Association, ADA is paying
6 my way to this meeting today, and I have no other
7 conflicts.

8 The ADA commends the committee for its
9 leadership to undertake a rigorous analysis
10 process to determine if scientific and medical
11 evidence demonstrates effectiveness and
12 appropriateness of bariatric surgery for the
13 Medicare population. The rapid rise in the
14 prevalence of overweight and obesity among all
15 segments of the U.S. population is of grave
16 concern, as the health and quality of life of
17 those afflicted plummets, and health care costs
18 and societal burdens continue to soar.

19 ADA has considered the evidence under
20 review in today's meeting and wishes to make the
21 following comments:

22 First, data for more than eight to ten
23 years post surgery is needed to have stronger
24 confidence in the ability of bariatric surgery
25 procedures to result in sustained weight loss,

1 improvement in comorbidities and long-term
2 survival, particularly in the elderly population.
3 Existing data indicate that short-term benefits do
4 exist, including the potential to improve quality
5 of life for obese patients.

6 Second, the existing data are
7 potentially biased in that studies and case
8 reports were generated by premier investigators at
9 major academic institutions and medical centers.
10 It's not clear if the rapid increase in surgeries
11 in the greater community is associated with the
12 same incidence of complications and adverse
13 events.

14 Third, it is unclear whether weight
15 loss is appropriate for obese elderly Medicare
16 beneficiaries without comorbidities. ADA
17 recommends a preventive approach that offers the
18 possibility of restoration of a healthy weight
19 before the comorbidities associated with obesity
20 become entrenched and organ damage occurs.
21 However, the contribution of obesity to mortality
22 in the elderly has yet to be conclusively
23 established. This suggests that a revision of
24 weight recommendations in older people,
25 particularly the upper normative range, seems

1 prudent.

2 The longitudinal study of aging found
3 that thinner older people were more likely to die
4 than those who were normal weight or overweight.
5 Mortality was actually lower in older people with
6 a BMI greater than 28.5. According to a 2001
7 analysis, 10 of 13 studies failed to show a
8 significant association between a BMI greater than
9 27 and mortality from all causes in 65-to-74-year
10 olds. In the few studies that did show an
11 association, the increased risk became apparent at
12 BMIs greater than 31, and the association
13 disappeared in those aged 75 years and older.

14 Therefore, ADA requests that the
15 Medicare Coverage Advisory Committee do the
16 following:

17 First, require coverage of pre and
18 post-surgical medical management of patients
19 undergoing bariatric surgery. Such management
20 should include a multidisciplinary team of
21 registered dietitians, psychologists, exercise
22 physiologists, and others who are qualified to
23 conduct nutritional and behavioral interventions
24 and physical activity counseling.

25 These interventions should also do the

1 following: Assess surgical candidates' ability to
2 comply with post-surgical protocols, minimize
3 short and long-term complications such as
4 gastrointestinal adverse effects, and prevent
5 weight regain.

6 We urge you to consider analysis of
7 insurance claims data to analyze both financial
8 and clinical outcomes associated with bariatric
9 surgery and require demonstrated clinician
10 adherence to evidence-based practice guidelines
11 and best practices for quality patient care and
12 optimal outcomes.

13 Thank you, members of the committee,
14 for giving ADA the opportunity to share our
15 comments about bariatric surgery for the Medicare
16 population.

17 DR. DAVIS: Thank you. Next,
18 Dr. Fischer.

19 DR. FISCHER: Good morning. I would
20 like to thank the panel for the ability to talk.
21 My name is Dr. Josef Fischer and I am testifying
22 on behalf of the American College of Surgeons,
23 which has 66,000 fellows. I am a regent of the
24 College. I am also the Mallinckrodt professor of
25 surgery at the Harvard Medical School and chair of

1 the Department of Surgery at the Beth Israel
2 Deaconess Medical Center. I am also the College's
3 representative to the Blue Cross Blue Shield
4 Association medical advisory panel, part of their
5 technology evaluation center. Bariatric
6 procedures are performed in my hospital although I
7 no longer do them. I have no conflict of
8 interests that I am aware of. My way is being
9 paid by the American College of Surgeons because I
10 am chairing the Health Policy Steering Committee
11 in Washington tomorrow.

12 The data from the Swedish Obese Subject
13 Study or SOS are cited in the Blue Cross Blue
14 Shield Association technical assessment and show a
15 16.3 percent decrease in total body weight six
16 years postoperatively for those undergoing
17 bariatric surgery. You have seen those slides
18 several times. This is compared with a .8 percent
19 increase in weight over the same period with
20 nonsurgical treatment.

21 You also have heard the technical
22 evaluation that CMS commissioned from the RAND
23 Corporation showed that the incidence of
24 comorbidities of hypertension, diabetes,
25 hyperlipidemia and sleep apnea following surgery

1 has improved, although at differing amounts and
2 rates depending when measurements are made. There
3 is a profound reduction in diabetes over a
4 5.5-year mean follow-up and the data also suggests
5 that the incidence of hypertension initially
6 drops, but by six years postoperatively it rises
7 virtually to preoperative levels, suggesting that
8 other factors are important as well.

9 It is not yet possible to answer some
10 of the crucial questions concerning the aged
11 population. According to the technical assessment
12 of obesity, treatment of obesity among the
13 elderly, the all-cause risk of mortality
14 associated with obesity diminishes with age,
15 raising questions about the benefit of reducing
16 obesity in this population.

17 Because there are age-related
18 differences in underlying physiology in general
19 and fat distribution in particular, one should be
20 cautious about generalizing the findings in the
21 younger population to those above 65 and certainly
22 among those who are above 70 years of age.
23 Furthermore, there are few studies among surgical
24 mortality and morbidity in the aged.

25 In September of 2000, the College

1 published a statement on recommendations of
2 facilities performing bariatric surgery which
3 addresses issues such as professional staff, the
4 operating room and hospital facilities. The
5 statement makes two points essential to the
6 success of bariatric surgery that are pertinent
7 here this morning. The first is that having a
8 full range of equipment and furniture appropriate
9 for the bariatric patient in the operating room
10 and throughout the hospital facility is essential.
11 The second is having an interdisciplinary staff
12 led by an experienced bariatric surgeon to provide
13 care and counseling throughout the extended
14 preoperative period and in the long postoperative
15 period. Preoperative psychiatric screening and
16 pre and postoperative nutritional counseling,
17 preoperative screening by internal medicine and
18 endocrinologists are the most important but not
19 the only services that we believe must be made
20 available. At the present time, coverage of
21 medically necessary pre and postoperative
22 counseling and screening varies from carrier to
23 carrier.

24 In conclusion, the College supports
25 programs for what has become an epidemic of great

1 public health concern to the nation, morbid
2 obesity. It urges CMS to continue to collect data
3 on outcomes for various bariatric procedures. In
4 addition, CMS must in our view take steps
5 necessary to assure coverage of preoperative and
6 postoperative care, especially preoperative
7 psychiatric screening and pre and postoperative
8 nutrition counseling. Thank you very much for
9 listening.

10 DR. DAVIS: Thank you. Dr. Dixon.

11 DR. DIXON: I'm John Dixon from
12 Melbourne, Australia. I'm a clinical researcher
13 in regard to obesity. I am a physician in a
14 full-time position heading up a research program.
15 I've received research grants and assistance from
16 INAMED Health, U.S. Surgical, Novartis Australia,
17 and Tyco. My costs for coming here are being
18 covered by INAMED Health, but I have other
19 commitments in North America.

20 Severe obesity, as you are aware, is a
21 serious disease. There's overwhelming evidence
22 that all procedures under consideration provide
23 significant weight loss when compared to
24 nonsurgical measures. We looked at systematic
25 reviews, we looked at the Swedish Obesity study,

1 but we also have to see, as David Flum mentioned
2 earlier, the numerous excellent observational
3 studies demonstrating significant sustained weight
4 loss at five years when other therapies provide
5 minimal effect at this time.

6 I wanted to mention briefly some of the
7 systematic review that was done by the Australian
8 College of Surgeons and Australian government with
9 regard to the laparoscopic adjustable gastric
10 band. This looked at 64 publications and its aim
11 was to compare this procedure with Roux-en-Y
12 gastric bypass and VBG, and to look particularly
13 at safety and efficacy.

14 You've seen this slide earlier. This
15 looks at the efficacy of the laparoscopic
16 adjustable band showing sustained weight loss
17 after five years and as you know, there are many
18 studies, this is Hadoff in 2001, there are many
19 studies showing weight loss beyond that time. For
20 up to the first two years, however, there is less
21 weight loss with the LAGB compared with the
22 Roux-en-Y gastric bypass and this systematic
23 review found no difference thereafter.

24 There were, however, differences in
25 short-term mortality and the mortality rate with

1 laparoscopic gastric bypass in the published
2 literature is one in 2,000, which compares with
3 one in 200 for Roux-en-Y gastric bypass. I won't
4 cover vertical banded gastroplasty. With this
5 procedure there is also a very low short-term
6 morbidity, and overall morbidity. It's
7 interesting that very similar to the death rates
8 that David Flum has found with gastric bypass,
9 there's a strong association of morbidity with the
10 number of patients in the series. Experience
11 counts in these series.

12 Now over the last seven years I have
13 spend a lot of time, including my doctorate, in
14 looking at and documenting the problems of obesity
15 and the effect of weight loss on obesity. I have
16 published numerous articles individually looking
17 at all these factors from Type 2 diabetes right
18 through all of those to probably what's most
19 important in your elderly population, quality of
20 life. And there is a strong body of evidence
21 supporting the improvement or resolution in
22 comorbidity with treatment.

23 Now, there is also a growing body of
24 evidence, and these are just some of the studies
25 that show that it's cost effective to treat

1 obesity. And certainly the British study showing
2 that the cost per quality adjusted life here of
3 less than \$11,000 for all surgical cases is
4 important, and there are further data on this to
5 come.

6 Mortality is also crucial, yet I think
7 not as important when it comes to the elderly
8 where quality of life is going to be the main
9 reason for intervening, but there are a number of
10 statements there. I must say that more recently,
11 we have looked at mortality data and it's very
12 consistent with the Canadian data and that of
13 David Flum, and it really does look like there is
14 now consistency that bariatric surgery in fact
15 saves lives.

16 Now, I want to talk a little bit about
17 some of the features that I think are important
18 with the LAGB system that allow low mortality,
19 allow broader applicability, particularly to the
20 elderly. There's low morbidity and mortality,
21 it's technically achievable, it's a short
22 procedure, short hospital stay. It's adjustable,
23 so it's able to be gently moved along. There's a
24 low risk of nutritional complications, and it can
25 be readily reversed.

1 Weight loss is our most important, is
2 our best treatment for those severely obese.
3 Those with morbid obesity, those with some serious
4 morbidity, the only treatment that's working is
5 bariatric surgery, and we should have this
6 available for all of our patients. Thank you.

7 DR. DAVIS: Thank you very much.

8 Dr. Allen.

9 DR. ALLEN: My name is Jeff Allen, I'm
10 associate professor of surgery at the University
11 of Louisville. I receive financial support in the
12 form of research as well as a paid consultant, and
13 I'm a preceptor for U.S. Surgical, Karl Storz,
14 Ethicon, and INAMED. In this particular instance,
15 INAMED has reimbursed me for my travel expenses.

16 I would like to give you hopefully a
17 more personal view of bariatric surgery with
18 emphasis on the gastric band. I would say that
19 perhaps many of the committee members are immune
20 to some of the squabblings and arguments we have
21 as bariatric surgeons, arguing whether a gastric
22 band or a gastric bypass, or a BPV is best, but I
23 think it's very refreshing to see everyone come
24 together and really advocating bariatric surgery
25 in general, and I feel equally as comfortable

1 advocating a gastric bypass up here, but today I'm
2 wearing a gastric band hat.

3 At the University of Louisville prior
4 to FDA approval, we became a C site trial site for
5 BioEnterics, which is now the INAMED band, and I
6 began placing bands in 2001 after a fellowship in
7 Australia, and we had a gastric bypass program in
8 place at that point. In that time period since
9 then we have seen 1,448 patients in our clinic.
10 About half have had gastric bypass and half have
11 had gastric bands, and of the gastric bypass it's
12 probably two to one laparoscopic to open. Our
13 patients are heavy, with a pre-op weight of 306
14 pounds with a BMI of 49.

15 I did look at our database and there
16 are some folks who we have operated upon and put
17 bands in who had Medicare as either their
18 secondary insurer or maybe even their primary
19 insurer and somehow or another we operated on
20 them. There are 16 of those, their pre-op weight
21 was 319 pounds, which are a little bit heavier,
22 and this ranges up to a patient with a body mass
23 index in excess of 86, so these are very heavy
24 sick people.

25 Comorbidities are what we see; all but

1 10 percent of our band patients have some
2 significant comorbidities. We use a technique
3 called pars flaccida, I mention it only to put a
4 picture on what we do. This is an empiric thing
5 that we've learned, perhaps even in the A trial,
6 the technique for placing and adjusting these
7 bands is different, it's simply improved.

8 It's important to know that there are
9 some unique and common complications with gastric
10 banding. Three of our patients, we've had to
11 convert to an open operation. That means 461 were
12 done laparoscopically, and that's a tremendous
13 benefit. There's a much higher rate of
14 laparoscopic completion than a gastric bypass. We
15 had one death, somebody we presumed to have a PE,
16 but it was likely due to an arrhythmia after a
17 negative autopsy. Post-op obstruction was a
18 complication that we saw fairly frequently
19 initially; we have not seen any in the past year
20 with the advent of a larger band. We're getting
21 better in how we do these things.

22 We've learned how to prevent
23 obstruction by taking that fat pad that you can
24 see down there, and you can see it
25 laparoscopically like this, and then sizing the

1 lesser curved fat pad. All these things are
2 simply improvement and it's a learning curve both
3 for me as an individual and as surgeons in general
4 doing these.

5 Gastric prolapse remains the most
6 common complication associated with this device.
7 We have about 5 percent, and it's simply when the
8 stomach herniates up through the band as you can
9 see here, and here on the laparoscopic picture,
10 here on an x-ray, and here endoscopically. I
11 think it's very helpful to see these pictures and
12 see exactly what we're talking about.

13 Sometimes the bands erode. This is
14 unusual, it's happened three times we've had to
15 take all those bands out. Apart from that, I've
16 taken about 15 bands out of these 400, including
17 some of the erosion, some of the obstructions I've
18 mentioned earlier, so it's certainly not a perfect
19 operation but I feel it's really the best one as
20 far as minimal complications, minimal mortality.

21 Now, looking at the Medicare specific
22 group, there were no deaths and there was one
23 patient who had a gastric prolapse. These seemed
24 to mimic our total group.

25 Weight loss data, 202 patients have

1 one-year follow-up; their average weight loss is
2 41 percent. In the Medicare specific group, seven
3 patients have one-year follow-up; their average
4 weight loss for some reason is better, 52 percent.
5 And if you look at pre-op SF-36 scores in this
6 group, 28 to begin, one-year post-op 47, dramatic
7 improvement, and we know the value of the SF-36.

8 In the big group, 91 patients have
9 two-year follow-up with an average weight loss of
10 50 percent, and seven patients at 60 percent. So
11 unlike the gastric bypass perhaps, the patients
12 lose weight a little built longer, and slower.

13 So in conclusion, we find that American
14 weight loss with gastric band in my hands is very
15 similar to what we see internationally. I think
16 the key is the low mortality and serious
17 complication rate makes it a particularly
18 attractive operation or surgical option for the
19 Medicare populations. There's a high rate of
20 laparoscopic completion and marked improvement in
21 physical function as seen in these SF-36 scores.

22 Thank you so much and we appreciate
23 your consideration.

24 DR. DAVIS: Thank you. Dr. Provost.

25 DR. PROVOST: David Provost. I'm

1 associate professor of surgery at the University
2 of Texas Southwestern Medical Center in Dallas.
3 We've received research grants as an institution
4 from Karl Storz, U.S. Surgical, and I have
5 received consultant fees from U.S. Surgical and
6 INAMED, and travel for this meeting was paid for
7 by INAMED.

8 What would like to speak about briefly
9 is our experience with laparoscopic banding
10 specifically in the Medicare population. We've
11 heard about the band that's placed around the top
12 of the stomach, it's adjustable, its perioperative
13 morbidity is low, and with this we can see a rapid
14 return to normal activity and gradual weight loss.

15 We have been placing the gastric band
16 since October 2001. Over that time period we've
17 placed 94 bands in Medicare patients. I have
18 broken these out into two groups. The first is a
19 group of patients who are over 65, we have 33 of
20 these patients. Their mean age was 67.8 years
21 with a range of 65 to 75, and their mean body mass
22 index was 48.1. The larger group, and this larger
23 group has actually been my experience with bypass
24 patients as well, the majority of Medicare
25 patients who we will operate on will be those who

1 are under age 65 on Social Security for long-term
2 disability. 61 patients with a mean age of 48.4,
3 higher BMI in this group, mean of 54, with a range
4 of 35 to 104.1. In these patients, all bands with
5 the exception of one which was placed at the same
6 time as the repair of a giant abdominal wall
7 hernia, and they were placed laparoscopically.
8 There was a single conversion, there were no
9 perioperative mortalities.

10 If we look at weight loss in these two
11 groups, again, the weight loss will be slower than
12 what's seen with the bypass. We have short-term
13 follow-up at this point, but what we do see is
14 good progressive weight loss in both groups.
15 Again, the weight loss begins to be a little bit
16 slower initially with the younger age group, but
17 they were a bigger group so if you actually look
18 at pounds lost, they are quite equivalent. At 18
19 months we see weight loss approaching 50 percent
20 in the entire cohort.

21 I would like to talk a second about
22 comorbidities. The first column, again, is the
23 percent of the total patient population who had
24 these comorbidities at the time of surgery; the
25 second column is those who have seen improvement

1 and/or resolution. Again, this was assessed in
2 those patients who were beyond three months
3 post-surgical follow-up, and what we see is that
4 there is a high prevalence of diabetes mellitus,
5 asthma, heart failure, joint disease, reflux,
6 hyperlipidemia, hypertension, back pain and sleep
7 apnea in these patients. The incidence of most of
8 these comorbidities seems to be, is higher in the
9 younger Medicare population. Again, these are
10 patients who are disabled primarily because of
11 their obesity and what we do see is marked
12 improvement in these comorbidities with weight
13 loss surgery.

14 Again, the band has not been available,
15 so I can't give you long-term results, we've seen
16 the foreign results.

17 So we have had good results in the
18 Medicare population with a low perioperative
19 morbidity and mortality, with good improvements in
20 their comorbidities. I would like to comment that
21 all of these patients for the most part had
22 comorbidities because that's what Medicare covered
23 at the time. There is a subgroup of patients who
24 we have operated on where we haven't been
25 reimbursed who had a comorbidity of joint disease

1 or impaired functional status, which was not
2 considered a significant comorbidity by Medicare.
3 But if you take a 30-year old who's on Social
4 Security because of the weight of 500 pounds and
5 impaired functional status, those are the patients
6 who you're looking at a lifetime of Social
7 Security and Medicare coverage, where we can get
8 them back into the work force at a young age, and
9 I think we've seen that several times in our
10 patient population.

11 Thank you very much.

12 DR. DAVIS: Thank you. Dr. Fisher.

13 DR. FISHER: My name is Barry Fisher.

14 I'm a bariatric surgeon in Las Vegas, Nevada, and
15 I'm here speaking on behalf of our patients who
16 need surgery but are deprived financially. My
17 pension fund has some stock in INAMED Health. I'm
18 a proctor and speaker for INAMED Health and
19 Ethicon Endosurgery, and I am in line to receive
20 an educational grant from Ethicon. My
21 transportation and lodging to this meeting were
22 paid for by INAMED Health. I have served on the
23 NIDDK advisory panel, a medical advisory panel for
24 INAMED Health, and chairman of a committee for
25 advances in bariatric surgery. Although I am

1 listed here as being associated with two medical
2 schools, I am a clinical teacher at those. We're
3 in a community practice.

4 I am here to address only three of the
5 questions found in the greater concerns, medical
6 versus surgical therapy, three different surgical
7 approaches, the resolution of associated medical
8 problems.

9 In 1995 there was a study published by
10 Louis Martin which unequivocally demonstrated the
11 failure of medical treatment for morbid obesity
12 when compared to the long-term success of surgical
13 intervention. You've seen the results of the SOS
14 study and this confirms what Louis Martin
15 reported. 89 percent at five years durability of
16 surgical treatment, 83 percent at seven years,
17 with complete return of lost weight in those
18 patients who were treated by diet alone.

19 We have been performing obesity surgery
20 for over 14 years, now limiting our practice
21 exclusively to bariatric surgery. We've had
22 experience with three different surgical
23 procedures and concurrently performed open,
24 laparoscopic gastric bypass and laparoscopic
25 banding, presently limiting our practice to

1 laparoscopic Roux-en-Y and laparoscopic banding,
2 as these seem to offer the best outcomes at the
3 lowest risks.

4 90 percent of our patients had one or
5 more comorbidity, 100 percent over the age of 65
6 had or exhibited one or more comorbidities in our
7 practice. In 2001 we adopted a detailed database
8 of our cases, now totalling 826 patients. We
9 analyzed this comparing the efficacy of gastric
10 bypass to lap banding. The first question we
11 addressed was whether open and laparoscopic
12 gastric bypass were equally efficacious, and this
13 slide demonstrates the analysis of our whole
14 practice.

15 It shows good long-term follow-up.
16 There was no significant difference in weight
17 comparing open and laparoscopic gastric bypass,
18 and the lap band patients' early weight loss was
19 clearly less than that of the Roux-en-Y patients,
20 with difference beginning to narrow with time.
21 All three produced excellent and durable weight
22 loss after three years in our programs.

23 We then further analyzed this group
24 using a matched pair case control model and in
25 this we matched patients by BMI and date of

1 surgery, and observed that there was no difference
2 subsequent when we analyzed it in terms of age and
3 preoperative weight in these matched pairs.

4 In this matched pair analysis we
5 confirmed that the gastric bypass is more
6 effective than the lap band during the first two
7 years with the difference in weight loss
8 diminishing with time. In addition, Pories
9 reported that gastric bypass patients regained
10 substantial weight in later years and many authors
11 have confirmed that. This may be understood as
12 these operations, the gastric bypass and the lap
13 band affect the patient in different ways and
14 their weight loss is therefore subsequently
15 different.

16 With regard to mortality and
17 complications in our practice since 2001, they are
18 shown in the following two slides. Mortality risk
19 seems to be higher with the gastric bypass.
20 Specifically, the one-year mortality of 0.68
21 percent compared to the zero mortality in our
22 patients at one year. And the subsequent
23 conclusion here, however, is that the return to
24 the operating room is different with a higher
25 return to the operating room after gastric band

1 than is observed in our laparoscopic gastric
2 bypass patients. In addition, there is a
3 significant difference in return to the operating
4 room between laparoscopic and open gastric bypass
5 due to wound complications.

6 With regard to associated medical
7 problems, it is clear that in the two large data
8 series that we analyzed when making our decision,
9 that there was no significant difference in
10 resolution of comorbidities. In our own practice,
11 42 percent diabetes reduced to 1 percent diabetes
12 at one year; we define it as less than 126 blood
13 sugar and a hemoglobin A1C of less than 6.

14 In conclusion, surgery is more durable
15 than medical therapy, there is no significant
16 difference in the efficacy, and both reduce
17 operative -- laparoscopic approach significantly
18 reduces operative complications due to the high
19 incidence of wound problems. Both laparoscopic
20 Roux-en-Y and lap band effectively reduce weight,
21 improve health and quality of life. Lap Roux-en-Y
22 may carry with it a higher mortality risk and the
23 Medicare population should be offered the choice.

24 Finally, Medicare pays for chronic
25 renal dialysis and other chronic conditions that

1 do not result in permanent cure and where the
2 outcome is dependent on patient compliance. You
3 have to apply the same yardstick in your decision
4 to cover treatment for this epidemic condition
5 because the country is watching. In addition, we
6 do not do Medicare patients because coverage
7 decisions are made by carriers. In our area,
8 every case has been challenged, and 50 percent of
9 our cases in our series were denied even though
10 they had clear evidence of comorbidities. This
11 committee and CMS must come out with a clear and
12 unencumbered statement of coverage. Thank you.

13 DR. DAVIS: Thank you. Dr. Hess.

14 DR. HESS: Good morning. I'm Dr. Hess,
15 I'm in private practice. I have no one supporting
16 me as far as finances of any kind and my trip here
17 was supported by my wife but she doesn't know it
18 yet. Thank you.

19 We do the biliopancreatic bypass, we
20 take out half the stomach and we bypass part of
21 the stomach so we can absorb fat here, we restrict
22 it here, we save the pylorus, everyone sort of
23 knows what it is. My statistics are like everyone
24 else's. We do have an average of 51 BMI in our
25 first 1,000 patients. My first ten-year weight

1 loss study was in April of 2003, has 120 patients.
2 We had 111 of them or 92 percent of those at ten
3 years, and that's a 76 percent excess weight loss
4 at that point. We also grade them by the
5 parameters because averages sort of give you funny
6 answers sometimes, 80/60 and so forth, but
7 everybody above 50 we call satisfactory. And we
8 took that same 111 patients and we have 76 percent
9 in the good to excellent range and we have 94
10 percent in the satisfactory range.

11 We also have some advantages to this
12 operation. It is a pyloric saving operation. It
13 has rare marginal ulcers and we had no dumping
14 syndrome, we don't particularly like the dumping
15 syndrome. We use no foreign materials, and it is
16 functionally reversible easily at the distal
17 Roux-en-Y, and if you operate the stomach the
18 right size you never have to touch it again,
19 because that's the tough spot.

20 Comorbidities, we cure them or we
21 prevent them or markedly improve them. Diabetes
22 type 2, we got a 98 percent cure rate. I think
23 they're 100 on sleep apnea, hypoventilation
24 syndrome was markedly improved, hypertension
25 improved, hypercholesteremia it absolutely

1 improves, and the others things do too.

2 This is our graph of 105 patients who
3 are all type 2 diabetics, their average blood
4 sugar was 200, this is a six-year graph. Everyone
5 here is normal after six months, none taking any
6 medicine, one half were taking insulin, one half
7 were taking a hypoglycemic agent. This guy had
8 severe sleep apnea, very heavy. He's 12 years
9 post-op and this is the way we think they should
10 look. We think we should be thinking about
11 long-term results.

12 We do have some major complications.
13 Gastric leak, 0.7 percent; revisions are between 3
14 and 5 percent, you don't know because time adds up
15 on these revisions; we had a half a percent we
16 reversed. A couple had cancer, a couple got into
17 drugs. We have had eight deaths out of over 1,400
18 patients, and 90 percent of those were the very
19 severely obese patient.

20 This is our last slide, just done last
21 month. It's 182 patients and we have 92 percent
22 follow-up at the 10-year point, some of these are
23 12 or 15 years, but at 10 years we got 75 percent
24 excess weight loss. We feel that we should be
25 looking at long-term, one operation for life and

1 not be reoperating these things, because that's
2 where all the risks are. Thank you very much.

3 DR. DAVIS: Thank you. Dr. Blackstone.

4 DR. BLACKSTONE: I'm Robin Blackstone,
5 I'm a community surgeon from Scottsdale, Arizona.
6 I do work as an educator for Ethicon Endosurgery
7 and I'm on the board of directors for Viking,
8 which is a medical device company. Other than
9 that, I guess you could say that my patients paid
10 my way here today through our practice. I have
11 not received any compensation for being here
12 today. Thank you very much for allowing us to
13 speak, and thank you, Mrs. Long, for all your
14 e-mails in regards to this.

15 I wanted to bring you the perspective
16 of a community practice which has been developed
17 since July of 2001. In that time we decided, both
18 myself and my hospital, that we would jointly put
19 together a program using the American College of
20 Surgeons guideline SAGES, and the American Society
21 of Bariatric Surgery guidelines, and the program
22 was developed along those guidelines. The program
23 philosophy focuses on education of the patient.
24 We established a prospective database in which
25 each patient is entered prior to surgery so that

1 we can track longitudinally all of their safety
2 data as well as resolution of comorbidities. We
3 have long-term follow-up as you'll see, to the
4 extent that we can in a three-year-old program,
5 and our goal is to create a community of support,
6 both psychological and medical for these patients,
7 and to communicate with the primary care provider
8 network that was going to care for these patients
9 long term.

10 The program I've just outlined here,
11 and I won't go into it further. Let me just say
12 that most of the patient have done an extensive
13 randomized trial of their own weight loss
14 therapies which has been self funded prior to
15 coming to see us, and those who have not done any
16 type of thing like this, will do it once they are
17 in our program where we have a dietitian and
18 psychologist who works with them during this
19 period regarding behavior modification, and to
20 show them that this can benefit them, so they use
21 surgery as a tool.

22 Basically in our program, we use the
23 National Institutes of Health criteria, which was
24 established, as you know, in the consensus
25 conference of '91. We initially operated on

1 18-to-60-year olds. We now have 47 patients
2 between 60 and 71 that we have operated on. They
3 need to have failed supervised medical weight loss
4 attempts, they have to have a good understanding
5 of the surgery and its risks, they have extensive
6 psychological evaluation including MMPI and other
7 tests, as well as interviews. And if they are
8 identified as needing some type of ongoing
9 support, they are referred into that prior to
10 surgery.

11 These are the two procedures that we
12 currently perform. The gastric bypass Roux-en-Y
13 was the first procedure that we began with after a
14 fairly extensive four-month period of training and
15 preparation for the hospital, which included of
16 course sensitivity training as well as equipment
17 issues. We also have enjoyed the dedication of
18 our hospital team in providing us with consistent
19 OR support, so we have pretty much the same team
20 operating, doing anesthesia on a daily basis,
21 which I think insures quality. We also have a
22 bariatric unit with nurses that are dedicated to
23 the bariatric patient group. In January of 2003
24 we began doing gastric band, we have now done
25 about 50 gastric bands, we have not done any in

1 the Medicare population.

2 These are, I wanted to give you an idea
3 of what our Medicare population look like as
4 compared to our total. 37 Medicare patients, 805
5 in SBC. This gives you an example of the
6 complications that we've enjoyed. We've had zero
7 30-day mortality in either group of patients, and
8 this data is through July of this year. It gives
9 you an idea of how that mortality is in context,
10 and I just wanted to point out that we do know
11 that even gall bladder surgery has some mortality
12 and compared to the mortality risk of these
13 patients long term, I think will be good.

14 I wanted to say, too, that our age
15 population is about the same as Medicare in
16 general. Most of our patients are younger, they
17 have a significant number of comorbidities. We
18 have zero patients in the Medicare population with
19 no comorbidities. Some of these comorbidities,
20 though, would not be actually reimbursed by
21 Medicare. This is the distribution of
22 comorbidities in our patient population, similar
23 to the distribution that you see nationally.

24 Our excess weight loss was 760 out of
25 805 patients followed up. Comorbidity resolution

1 rates in our Medicare population parallel what
2 you've seen demonstrated in the meta-analysis and
3 other studies. And our diabetes resolution, out
4 of 164 diabetics treated through the end of July,
5 you can see that 31 remain on oral therapy after
6 17 months, and most have resolved that and this
7 was the mechanism of their resolution.

8 In the arena of social outcomes, 26 of
9 37 patients were able to be contacted. Four
10 patients were working full time. Again, this is a
11 disabled young population who is mostly not
12 working.

13 In conclusion, most of the Medicare
14 population that are being treated are between the
15 ages of 25 and 64. They have a higher degree of
16 comorbid disease and in our group 44 percent were
17 diabetic versus about 21 percent in our study at
18 large. Surgical therapy was the most effective
19 treatment. It does consider risk, but the risk of
20 not treating is higher. Outcome and process
21 improvement will be hallmarks of a program that
22 Medicare treatments and other payers' patients
23 should be treated through.

24 We have just applied for the ASBS
25 center of excellence designation, and have been

1 designated a center of excellence by a very large
2 employer and a couple of other insurers. And I
3 think a high volume comprehensive community with a
4 continuum of care and this kind of comprehensive
5 treatment, really is your best way to treat these
6 patients in a safe environment. Thank you.

7 DR. DAVIS: Thank you. Dr. Bessler.

8 DR. BESSLER: Good morning and thank
9 you to the panel for the opportunity to present to
10 you. My name is Marc Bessler, I am an assistant
11 professor of surgery at Columbia University. By
12 way of conflicts, I have received research support
13 from Tyco, United States Surgical, TransNeuronics
14 Corporation, and my trip today was covered by
15 INAMED.

16 I briefly just want to address the
17 issue of comorbidity resolution and safety of
18 these operations. We talked about the operations
19 already. We undertook a study to compare the
20 outcomes of both gastric bypass to adjustable
21 gastric banding and not so much to point to one
22 versus the other as better, but to show that they
23 are both potential options for patients.

24 We reviewed 572 patients that were
25 operated on since we started doing banding, which

1 was part of the C trial in February of '01. A
2 quarter of those patients approximately elected to
3 have gastric banding and the other three quarters
4 had gastric bypass, mostly laparoscopically. We
5 also did a matched case control which I'll show
6 you.

7 This is the weight loss data. The
8 square is looking at the excess BMI loss and the
9 circle is looking at excess weight loss. You can
10 see at two years 46 percent excess weight loss for
11 banding and 65 percent excess weight loss for
12 gastric bypass, very similar to all the other data
13 I guess you've seen today, except again, this is
14 from the United States and compared in the same
15 center done by the same surgeons with the same
16 definitions, the same scale, et cetera and so
17 forth, so it's not compared across studies and I
18 think adds some value.

19 This is our matched trial because the
20 patients who had the lap band were slightly older
21 by two years and slightly heavier by two BMI
22 points, and we wanted to control for that, so when
23 we matched for that the results as you can see are
24 pretty much the same.

25 We looked at sweet eaters versus

1 non-sweet eaters, and found no difference in our
2 weight loss in our gastric banding or our gastric
3 bypass patients whether they were sweet eaters or
4 non-sweet eaters, and I think that issue can
5 probably be put to rest at this point with a large
6 study that was also published from Australia.

7 The BMI does seem to affect weight
8 loss. This is statistically lower BMI -- I'm
9 sorry, lower percent excess weight loss if the
10 patient has a BMI over 50 with gastric bypass, but
11 it didn't reach significance if the patient had a
12 BMI over 50 with banding, and that may be due to
13 the different mechanisms of these operations over
14 time.

15 What's not up here, I guess this was
16 added, was the comorbidity resolution. Up front,
17 40 percent of our patients had hypertension, 21
18 percent diabetes, 30 percent approximately
19 hyperlipidemia, and in the mid to high 60s
20 arthritis, and that was similar between the band
21 and bypass groups. We had a slightly higher
22 incidence of urinary incontinence and obesity
23 hypoventilation syndrome in our gastric bypass
24 group, and again, that may be due to the female
25 predominance and the weight difference.

1 The resolution of those comorbidities
2 between the two groups were identical except for,
3 and I want to find the data for you here,
4 hypertension was 71 percent resolved in our
5 gastric bypass group and that was higher, and also
6 a higher resolution was 90 percent for
7 osteoarthritis, 90 percent for GERD, and 90
8 percent for urinary incontinence, versus in the
9 70s for our adjustable banding, but again,
10 significant resolution of these diseases. I think
11 that it's clear that these operations benefit our
12 patients, 90 percent of whom have comorbidities
13 and equivalently so.

14 The last important point, also perhaps
15 previously made, is that risks of these
16 operations, we had no mortality in either group,
17 but the morbidity was 15 percent for our gastric
18 bypass patients and 6.6 percent for our lap band
19 patients. Although more patients returned to the
20 operating room for relatively minor procedures
21 with the lap band, the major complications were
22 higher in the gastric bypass group, perhaps
23 offsetting the difference in weight loss. I think
24 both these and other operations need to be
25 available to our patients because it really does

1 improve their quality of life, as you have already
2 seen, and I thank you for the opportunity to
3 present.

4 DR. DAVIS: Thank you. Dr. Still.

5 DR. STILL: Good morning. My name is
6 Christopher Still. I am the medical director at
7 the Center for Nutrition and Weight Management at
8 Geisinger Medical Center in Danville. I do serve
9 as a medical consultant for Ethicon in a scientist
10 advisory board. I have no other conflicts of
11 interest and I paid my own way this morning.

12 What I would like to thank the panel
13 for allowing me to come to present is obesity
14 treatment and outcomes of obesity treatment in the
15 rural community setting. Just to give you some
16 historical perspective, we started our
17 comprehensive management program in 1994 and in
18 2001 we added the modality of bariatric surgery.
19 We do live in a rural community place and we offer
20 services to 31 counties in central Pennsylvania.
21 We have a comprehensive weight management program
22 that includes diet, behavior modification,
23 exercise, pharmacotherapy if weight loss plateaus,
24 and then if appropriate, bariatric surgery after a
25 six-to-eight month process. We do have a

1 multidisciplinary team approach including myself
2 as the medical director; we have a bariatric
3 medicine fellow; we have two physician assistants,
4 three nurse specialists, five registered
5 dietitians, two behavioral psychologists, four
6 bariatric surgeons, and a myriad of research
7 coordinators and technicians, and also an
8 insurance coordinator.

9 Just to show you the overall statistics
10 of our weight management center, the average BMI
11 of all comers is 46 with a corresponding weight of
12 284 pounds. 38 percent of these individuals
13 suffer from diabetes, 27 percent from obstructive
14 sleep apnea, 18 percent from steatohepatitis or
15 fatty liver, and 22 percent from depression. Our
16 active number of patients in our database is about
17 4,300. We see about 45 to 50 new patients per
18 week and we operate on about 10 to 15 patients per
19 week. So clearly surgery is not our main focus of
20 our comprehensive weight management program, but
21 it is the most effective modality, as I will show
22 you. Approximately 9.2 percent of all of our
23 patients are Medicare patients.

24 Just to show you some medical
25 management one-year outcome data, as I said, 9.2

1 percent of these were Medicare patients. 38
2 percent of the medical management were diabetic.
3 The average weight loss was nine pounds or a
4 reduction in body mass index by 1.2. There was a
5 modest but important reduction in hemoglobin A1C
6 in the medical management from 8.8 initially to
7 7.4 after one year, which represented a 1.4
8 percent drop. It is significant but unfortunately
9 in medical management, it's just not long lasting,
10 and I think from an internist, that's where the
11 surgical outcomes are much more impressive for
12 that.

13 Now if we look at the Medicare
14 population specifically in the surgical outcomes,
15 the average weight was 322 pounds, the average BMI
16 is 53, the average age in our Medicare population
17 was 51. The average weight loss was 86 pounds and
18 losing minus 14 body mass indices. Out of the 713
19 surgeries that we've completed since 2001, 10
20 percent or 71 were from Medicare patients. 84
21 percent of the Medicare patients had hypertension,
22 68 percent had diabetes; as you recall, 38 percent
23 in our medical management of all comers had it.
24 52 percent had high cholesterol, 40 percent had
25 reflux and obstructive sleep apnea, and 14 percent

1 had depression.

2 As I showed you, the statistical
3 differences between medical and surgical weight
4 loss was about nine pounds versus 83 pounds.
5 Surgical management of the resolution of the
6 entire population, 84 percent had normal
7 hemoglobin A1C after two years. After one year it
8 went from 8.8 to 6.7, and then two years a 6.1
9 percent hemoglobin A1C. Hypertension was resolved
10 68 percent of the time. Obstructive sleep apnea,
11 these are pre-and-post sleep studies, resolved or
12 normalized in 84 percent of individuals. And
13 fatty liver, steatohepatitis normalized in 70
14 percent of individuals.

15 We've also published data on monthly
16 cost reduction in diabetic and hypertensive
17 medications pre and post-surgery. This is in the
18 Medicare population. The average cost for monthly
19 medications for diabetes and hypertension was \$192
20 per month preoperatively and post-surgical was
21 \$36.35, with a monthly savings of \$156.

22 So in conclusion, I believe that
23 bariatric surgery is a highly effective treatment
24 for morbid obesity, and most importantly in
25 resolving its comorbid medical problems, and it

1 should be offered to patients who fail
2 conservative management. Compared to medical
3 management, surgery results are more profound and
4 long term than medical management.

5 However, to insure the optimal outcome,
6 I think surgery needs to be performed in a
7 multidisciplinary program for the best results.
8 At least in our experience, the community or rural
9 setting suggests that good outcomes can certainly
10 be achieved both in the general and the Medicare
11 population, and I believe that bariatric surgery
12 is a key in the spectrum of treatments and
13 modalities for the treatment of obesity. Thank
14 you.

15 DR. DAVIS: Thank you. Dr. Schoelles.

16 DR. SCHOELLES: Hi. Karen Schoelles.
17 I'm an internist and geriatrician. I am an
18 employee of MetaWorks. We performed the
19 meta-analysis, the systematic review of the
20 literature and the meta-analysis that formed the
21 basis of Dr. Buchwald's manuscript in JAMA. Our
22 work was sponsored by Ethicon Endosurgery and my
23 travel expenses for coming here today were
24 supplied by Ethicon Endosurgery. I'm currently a
25 student at the Harvard School of Public Health and

1 living on a grad student's budget again, so I
2 accepted.

3 The key question we were asked to
4 address in our, or in this particular part of a
5 larger effort of looking at the bariatric surgery
6 literature was on the question of how
7 comorbidities are affected after bariatric
8 surgery. We performed a search in the usual way
9 that has become recognized in the systematic
10 review process. Our company was founded by Dr.
11 Thomas Chalmers and Dr. Susan Ross, and we have
12 built upon the work of the Cochran Group as well
13 as other EPCs doing work for AHRQ.

14 We did the search for this literature
15 review beginning in 1990 and the cutoff date was
16 June 5th of 2003. We were building an entire
17 database catalog of all the bariatric surgery
18 literature in that time period with the
19 exclusions, the primary exclusions being studies
20 that reported on fewer than ten patients or had
21 less than 30 days of follow-up. Within that
22 larger catalog we sought those studies that had
23 some outcome pertinent to one of the comorbidities
24 of interest. We initially were trying to also
25 look at health care economics data and some of

1 those studies have some of the outcomes but not
2 all.

3 There is a lot of difficulty with this
4 literature and I think the presentations today
5 made me think about how valuable registries are in
6 this field. There are many issues with the way
7 the number of patients at any given time point are
8 reported. We didn't always know whether there was
9 right sensoring, in other words, patients who only
10 recently were operated and in which cases there
11 was attrition lost to follow-up.

12 What we settled on as our best
13 compromise was to pick the latest time point at
14 which at least 50 percent of the described cohort
15 was being followed and for which there were
16 outcomes. In this process we screened over 2,700
17 abstracts and this particular data set included
18 134 studies with 91 overlapping publications. We
19 make an effort not to double count people. And in
20 this set, again, we were choosing papers based on
21 the reporting of some outcome pertinent to
22 comorbidity.

23 As you can see, there were a large
24 number of patients. The age range reported in the
25 papers, in other words the range of the ranges,

1 went from age 11 to age 73. There were seven
2 studies that included enough older patients to
3 have a mean age over 50, and four of those studies
4 had a minimum age of 50. 25 of the studies in the
5 entire set included patients over 65 but did not
6 report separable outcomes.

7 These are some so-called forest plots
8 of the meta-analytic results. As you know from
9 hearing most of this through the day, the change
10 in weight either measured by BMI or absolute
11 weight loss in kilograms is significant. We were
12 able to capture some results on populations
13 specifically described as either diabetic or
14 glucose intolerant in some way, not always by the
15 specific definition that internists might use, but
16 the data is limited and yet, there were
17 significant decreases in hemoglobin A1C in the
18 diabetic population. Glucose results both overall
19 and within the diabetic population were quite
20 impressive as well. The decrease in total
21 cholesterol was less so but the change in
22 triglycerides was fairly significant.

23 You've heard these numbers throughout
24 the day today and these are the other overall
25 numbers for resolution or improvement in the

1 comorbidities and I won't belabor those again, but
2 again, they are high numbers.

3 DR. DAVIS: Thank you very much.
4 Dr. Rabkin.

5 DR. RABKIN: My name is Robert Rabkin,
6 I am speaking as a bariatric surgeon in private
7 practice in San Francisco. In the past I've
8 received funding from Tyco and Johnson & Johnson,
9 but my appearance here today is not paid for by
10 any other entity other than my patients.

11 I want to skip forward to question five
12 just to say that I'm highly confident that it's
13 very likely that results of bariatric surgery can
14 be generalized to the Medicare population as
15 practiced in a community-based, or by
16 community-based providers.

17 I want to address the construction of
18 question four. The most important concept I want
19 to convey today is that the duodenal switch or DS
20 procedure is a vastly different entity than other
21 weight loss procedures. The weight loss is
22 greater and more durable and due to the preserved
23 gastric anatomy, there's no dumping, gastritis or
24 ulceration. These elements distinguish the DS
25 from the Roux-en-Y gastric bypass, the lap band,

1 and notably from the biliopancreatic diversion or
2 BPD procedure. As important, there are
3 significant quality of life issues that are
4 improved with the DS compared to the other
5 procedures.

6 I have included in my slides some
7 forerunners of the DS because they're sometimes
8 confused with the modern DS procedure of Dr. Hess.
9 Of historical interest only, the JIB was developed
10 in the 1950s and is no longer performed. We've
11 already heard about the other weight loss options
12 so we can move on, and again, the vertical banded
13 gastroplasty, we can move on. The lap band, like
14 the vertical banded gastroplasty, is a restrictive
15 procedure.

16 We all agree that the foundation of
17 this is weight loss. The Roux-en-Y gastric bypass
18 is the most popular procedure today, but it has
19 limitations because it is primarily restrictive.
20 Initial quality of life is compromised by
21 extremely small meal volumes as well as a dumping
22 syndrome, marginal ulceration and gastritis.
23 Accommodation to the restrictive effect occurs in
24 many patients, gradually allowing for larger
25 meals, and can result in substantial weight

1 regain. There is a lifetime contraindication to
2 ansates, which are among the most commonly used
3 medications today, both prescribed and over the
4 counter, and this problem is caused by the
5 juxtaposition of acid producing mucosa to small
6 bowel at the proximal anastomosis of the Roux-en-Y
7 gastric bypass, which is avoided by the
8 construction of the duodenal switch for the many
9 formerly obese patients who continue to suffer
10 joint problems of exclusion of ansates is a
11 serious lifelong problem.

12 As I mentioned, the nomenclature can be
13 confusing. The biliopancreatic diversion or BPD
14 developed by Dr. Scopinaro in the 1970s is not the
15 modern duodenal switch procedure. This is
16 important and we will review the distinctions in a
17 moment. This is a distal Roux-en-Y gastric
18 bypass, which adds a malabsorption component to
19 Roux-en-Y gastric bypass, but does not, has no
20 effect on the disadvantages that we mentioned as
21 far as the Roux-en-Y gastric bypass.

22 The modern duodenal switch constructs a
23 two-shaped stomach for moderate restriction and
24 limits the length of the common channel to reduce
25 absorption. Reduced stomach capacity produces the

1 initial dramatic weight loss, and gradually the
2 stomach size increases to permit larger meals, at
3 which point malabsorption takes over to maintain
4 weigh loss. As I mentioned at the outset, DS
5 advantages include normal eating habits, no
6 dumping and normally functioning stomach with no
7 marginal ulcers. There's no blind pouch as seen
8 in the Roux-En-Y gastric bypass. And upper GI
9 x-rays and endoscopy and so forth can be done
10 noninvasively to evaluate the entire stomach.

11 The disadvantages, while the duodenal
12 switch is a more complex procedure, somewhat
13 increased operative type, and the resected lateral
14 portion of the stomach can't be reinserted.

15 Our practice primarily offers
16 laparoscopic duodenal switch using techniques
17 which I developed in 1999. To date we have
18 performed more than 840 laparoscopic DS
19 procedures, which is the largest such series, with
20 one operative mortality. Among our initially
21 published 345 patients, there were seven
22 conversions to open laparotomy and 14 reoperations
23 for infection, leak or stricture. The resolution
24 of comorbidities is similar to the other
25 presentations.

1 This demonstrates our two-year weight
2 loss reported in our first published series, and
3 within two years the average patient was within 10
4 percent of ideal body weight. Our heaviest
5 laparoscopic duodenal switch patient weighed 656
6 pounds, another laparoscopic duodenal switch
7 patient had a higher BMI of 118. Neither had
8 surgical complications and both are enjoying a
9 vastly improved quality of life.

10 Thank you very much for your time.

11 DR. DAVIS: Thank you. Sondra Albers.

12 MS. ALBERS: Hello. I am retired from
13 the University of California San Diego, went out
14 on disability, I'm no longer on disability because
15 I'm no longer disabled. My travel here was paid
16 for by INAMED. What they didn't know is I would
17 have paid them or you for the opportunity to speak
18 in the hopes of helping other seniors have the
19 quality of life which I now enjoy.

20 I tried and succeeded at every diet
21 that was made, I always got there, sometimes for a
22 day, sometimes for a month. My pre-band weight
23 which they left off there was 210 pounds. My
24 comorbidities were hypertension, which I took
25 three medications a day for, and still had high

1 cholesterol, asthma, one medication, to
2 inhalators, and lots of emergency room visits.
3 Heart disease on two medications, GERD, one
4 medication. They knew me at the ER, the doctors'
5 offices, the nurses, they all knew me, much beyond
6 my age.

7 I'm 70 years old now and I was 66 years
8 old when I had the band done. I had it done in
9 Mexico because this was pre-FDA approval and I was
10 not a candidate for gastric bypass due to risk
11 factors my doctors felt at the time. My initial
12 weight loss within one year was 100 pounds. I did
13 regain 17 pounds due to the band slippage, but I
14 have lost nine of those now that they were able to
15 put some fill in. I had other medical problems
16 and had to postpone fill. And since that was done
17 I've lost two more pounds, so I am seven pounds
18 from where I was and they've maintained that
19 for the entire time without a lot of effort,
20 by the way.

21 And I'm off all medication except for
22 two. I take one Avapro a day and one
23 Isosorbidedemonote. I have not had an attack of
24 asthma since the day I woke up in the hospital. I
25 did not know what breathing was. I know now what

1 it is to breathe. My cholesterol levels are
2 normal without medication. The GERD is gone with
3 the exception of occasional bouts when I do eat
4 spicy foods, when I know it's going to happen.

5 The band slippage appeared in January
6 of '04. It was repaired laparoscopically the same
7 day, the band was not compromised so they did not
8 have to put another band in, and the treatment is
9 continuing. I have had no other complications
10 with the lap band.

11 There is always a risk to surgery and
12 especially when you know that you're overweight,
13 obese, morbidly obese, you know that you have a
14 higher risk, but I'm still here and I want to tell
15 you something. I wouldn't be here. My internist
16 believes that, I believe it. If this hadn't been
17 done to me, I wouldn't be here today. I would
18 like to request of you that you do not forget that
19 seniors not only can have a better quality of
20 life, I dance, I skip through malls with 18 of my
21 grandchildren, some of them are embarrassed by it,
22 and I have a wonderful life. And there's a glint
23 in my husband's eye that I didn't see for a while,
24 and that's nice too by the way. So I'm asking,
25 please think about this and do it. We give back.

1 We give it back in volunteer work, we give it back
2 in quality of life, and not having our children or
3 our grandchildren having to take care of as soon
4 or as much. I thank you and I hope this helps.

5 DR. DAVIS: Thank you. Pamela Rogers.

6 MS. ROGERS: Good morning. My name is
7 Pamela Rogers and I am here today to speak on
8 behalf of myself as a person who has had bariatric
9 surgery. I don't have any financial or other
10 conflicts of interest and I've paid for this trip
11 myself.

12 In response to the MCAC question one,
13 the effectiveness of bariatric surgery as compared
14 to nonsurgical treatment, I would like to tell you
15 my story. As an obese person most of my life, I
16 spent countless numbers of years and time trying
17 to lose weight through dieting and nonsurgical
18 treatments. While some efforts had been
19 successful, I would always gain more weight back
20 than I had lost, so in the short term they were
21 successful but in the long term they were not. I
22 would quickly regain the pounds and as I aged,
23 these failures clearly outweighed the successes.

24 In early 2004 I was at my highest
25 weight, around 275 pounds. My blood pressure had

1 become unstable and I was at risk for type 2
2 diabetes. Together with my primary physician, I
3 decided something needed to be done. In an effort
4 to make an informed decision regarding bariatric
5 surgery, I reviewed most of the scientific
6 literature that was available at that time and on
7 April 6, 2004, I had the laparoscopic Roux-en-Y.

8 So to answer you question, if there's
9 evidence that supports the effectiveness of
10 obesity, and again, this is only anecdotal, but I
11 determined through my readings that it did support
12 bariatric surgery. Right now I'm seven months out
13 from surgery and I have lost approximately 90
14 pounds and I'm confident that the weight loss will
15 continue and eventually I'll get to what's
16 considered a normal weight. I started out with a
17 BMI of 43.3, considered morbidly obese, and today
18 I have a BMI of 29, just overweight. I
19 continuously maintain a normal blood pressure and
20 am no longer taking previously prescribed
21 hypertensive medications. I have a blood glucose
22 reading of 80 and a total cholesterol of 139, well
23 within normal readings. Not only have these
24 changes contributed to my physical well being, I
25 have developed a philosophy of liking myself.

1 These changes have also instilled a personal
2 commitment to take care of myself by exercising,
3 eating healthy foods, taking my vitamins, and
4 making these changes permanent.

5 I'm going to address question two and
6 question three together. Life is a calculated
7 risk, all of the areas mentioned in the question,
8 sustained weight loss, long-term survival,
9 short-term mortality and resolution of comorbid
10 conditions were all factors in my decision to have
11 bariatric surgery. After reading the papers by
12 Clements, Smith, Rashid, Buchwald and others, I
13 was convinced of improvement in comorbid
14 conditions, especially in hypertension and type 2
15 diabetes.

16 Investigating the mortality data showed
17 that the short-term mortality rate of .5 percent
18 for gastric bypass was an acceptable rate, a rate
19 similar to gall bladder surgery and slightly
20 higher than having an unruptured appendix removed.

21 While research on long-term survival
22 was limited, visiting obesity chat rooms, I often
23 met people that had surgery in the 1970s and were
24 doing marvelously, so that helped convince me that
25 these people, it was a long-term thing, that these

1 people led healthy productive lives, and I could
2 do so too. Many of these people that I met in the
3 chat rooms also had comorbid conditions, all of
4 which were resolved or improved after surgery.
5 For those reasons I chose to pursue surgery as my
6 last resort, as my last hope for normalcy.

7 As we know, there are many different
8 bariatric surgeries and I have undergone a
9 laparoscopic Roux-en-Y, the only surgery that my
10 insurer covers. I just wanted to caution you that
11 while there are many different surgeries, I would
12 hope that CMS would come up with a list of
13 surgeries that they're going to cover. What
14 happened to me was that my insurer, after they
15 preapproved me, decided not to cover it because my
16 surgeon gave me a 150-centimeter y limb and the
17 insurer decided not to cover it after I had the
18 surgery, so I'm paying for it myself.

19 And I guess in summary, because my time
20 is up, I just want to thank you for having me here
21 today and as an individual who has had Roux-En-Y
22 surgery and researched all of the options, I
23 believe that laparoscopic Roux-en-Y surgery
24 affords morbidly obese individuals a sustained
25 weight loss, long-term survival and resolution of

1 comorbid conditions that they deserve. Thank you.

2 DR. DAVIS: Thank you very much.

3 Eldith Willis.

4 MR. WILLIS: My name is Willy Willis.

5 I am a retired heavy equipment operator and
6 grading superintendent for a grading contractor in
7 Ventura, California. I have no -- I've got to
8 read this because I'm talking to doctors. I'm
9 used to talking to dirt workers where I can cuss
10 at them and stuff, you know. Anyway, nobody owes
11 me nothing, I don't owe anybody nothing, INAMED
12 paid for my trip out here, okay? And they asked
13 if I'd talk to you and I said yeah, I will give
14 you my experiences.

15 My experience was, I'll give you a
16 little bit of my medical background before I had
17 this surgery. I woke up many mornings with my
18 feet hurting, burning, tingling. A couple months
19 later I go to the doctor, it was a neuropathy, had
20 diabetes. He says get the weight off, good
21 doctor, I talked to him like I would a
22 construction worker and he talks back to me the
23 same. He says I told you everything you've got to
24 do, but you're not doing it. I have had a
25 lifetime of not doing diets and I have been in a

1 lifetime of diets, and they all work, but they all
2 get right back on. So after my diabetes I still
3 wasn't losing the weight, the neuropathy was just
4 as bad, and my doctor told me to go see Dr. Billy
5 in Ventura.

6 I went to one of his meetings there
7 where they talked about the lap band and the
8 gastric bypass. My wife says you're not getting
9 any of them. So I took her back, we decided, she
10 decided on a lap band, because I wanted to lose
11 the weight fast, and the gastric bypass he says
12 you'll lose the weight faster. Well, I think I've
13 done as good as most gastric bypasses. I had the
14 lap band, and a year and a half later I have lost
15 180 pounds.

16 I was talking to one of the doctors
17 that talked up here and he said how do you do
18 that? I said, do what your doctor tells you, you
19 know, because I didn't know that Medicare was
20 going to this bill or not pay it. I know that I
21 had went as far as I could go and I didn't want to
22 live anymore. Let's see.

23 Before surgery I really didn't have a
24 life, I was over 425 pounds, now I'm 250. I got
25 up in the morning since I was retired. I couldn't

1 walk, I had a back surgery, a knee operation, I
2 have had all kinds of medical problems. The back
3 surgery helped but the doctor told me the same
4 thing, lose weight, you'll do better. I ended up
5 having the lap band from Dr. Billy. I feel great.
6 It has changed my life in every way you can think
7 of, and my wife can tell you some of those ways,
8 but I wish she wouldn't. It helped everything,
9 everything. And you know, that's without Viagra
10 or anything like that either.

11 All I did when I got up in the morning
12 was eat, watch television, walk by the
13 refrigerator, open the door and look at the same
14 food I had just seen ten minutes ago, so I'd get
15 another bite of it. And I ballooned. I mean, my
16 head looked like a giant bowling ball. After I
17 started losing weight, you feel better so you
18 start doing more. And now if you can find me in
19 front of a television for more than 20 minutes at
20 a time to watch news, you're doing good, because
21 I'm always working doing something.

22 Billy says do you exercise? I say no.
23 I don't lift weights, I don't do anything, but I
24 work all the time. Since then I have built a
25 little workshop in my garage and I'm making

1 furniture, I'm doing this, I'm doing that, I grow
2 a garden, I mow the grass, trim the grass, pull
3 the weeds. I do a little bit of everything. We
4 bought a Harley, which I always wanted but never
5 did. Now we go on Harley runs, me and the wife,
6 enjoy that thoroughly. I can't wait to get back
7 and hope it's sunny in California where I can ride
8 it this weekend, because I just got back from
9 Europe, Italy and Spain, two days before I come
10 here. And wish I hadn't told Medicare, or not
11 Medicare, but INAMED that I would come, because I
12 was so stinking tired when I got home I didn't
13 want to travel anymore.

14 But I'm glad I come, I've learned a lot
15 just from listening to these doctors talk. And
16 let's see. I really didn't have a quality of life
17 until I had this surgery. You can't imagine,
18 well, I guess you doctors can because you see guys
19 over 400 pounds, but my dad and everybody involved
20 around me, my family was worried, my wife was
21 worried, and she thanks INAMED, she told Vern back
22 there, I want to thank you, you saved my husband's
23 life.

24 And the only thing I really have to say
25 to people that need this surgery, Medicare, they

1 paid for my room, but they should pay more. For
2 the simple reason they have saved more than they
3 was paying on medicines for me in this last year
4 and a half. I was taking 19 medicines a day,
5 that's how bad of shape I was in, 19 medicines a
6 day. I was so sick of taking pills and squirting
7 stuff up my nose so I could breathe because I was
8 too fat, everything. And I know in a year and a
9 half, they made more than enough to pay for that
10 hospital. So please add the wording so all these
11 doctors, I've heard the same thing, if the wording
12 was right, they would know who could get it, who
13 couldn't get, and whatever.

14 Anyway, that's my story, I'm sticking
15 to it. Thank you very much.

16 (Applause.)

17 DR. DAVIS: Thank you very much. When
18 you're riding that Harley, are you wearing a
19 helmet?

20 MR. WILLIS: I don't want to, but I've
21 got to.

22 DR. DAVIS: Thank you very much to all
23 those presenters, and here's the schedule. It's
24 20 after 11 on my watch, so we're a little bit
25 behind schedule, but my plan would be to allow the

1 committee members to ask questions of those who
2 have presented so far for about 15 minutes. Then
3 we have six more people who have signed up for the
4 open public speaker session. We're going to ask
5 them to limit their remarks to three or four
6 minutes, like those who have preceded them. So if
7 we start with that at about 25 to noon, that
8 should take us to noon when we'll take a break for
9 lunch, and then we'll have plenty of time after
10 lunch for the committee to ask more questions of
11 the presenters and then to have open discussion
12 and move toward voting on the questions that we
13 have been asked to address. So, let me just open
14 it up for questions. Yes please.

15 DR. OWEN: This question is actually
16 posed to the professional presenters who declared
17 a conflict of interest. I'm curious if your
18 slides were developed or reviewed by any of the
19 firms that supported your attendance.

20 (Negatives from all presenters from the
21 floor.)

22 DR. DAVIS: Yes, Dr. Klein.

23 DR. KLEIN: This is a question for
24 Dr. Pories and Dr. Flum. You had both mentioned,
25 or one had mentioned that there is a learning

1 curve where you do fewer procedures at an
2 increased rate of mortality, and Dr. Pories, you
3 mentioned this idea of centers of excellence to
4 really make sure proficiency is performed. Are
5 you recommending that only centers of excellence
6 or experienced surgeons be allowed to perform
7 bariatric surgery.

8 DR. PORIES: I think that's a good
9 recommendation. I think that surgeons must be
10 adequately trained before you do it, this is
11 difficult stuff. And I think you ought to look at
12 it the way we look at cardiac surgery, where
13 people have to have adequate training and
14 proctoring before you get good results.

15 DR. KLEIN: And just along with that,
16 then, how would you diagnose a competent surgeon,
17 would it be number of procedures, clinical
18 outcomes, or they have to be within a center of
19 excellence?

20 DR. PORIES: Well, the centers of
21 excellence have developed some tough standards,
22 and one of the standards is that a surgeon must
23 have a minimum number of 50 cases before he's
24 considered part of the center of excellence, and
25 the center of excellence must perform a minimum of

1 125 cases per year.

2 DR. DAVIS: If I could just pick up on
3 that, this gets to the generalizability question,
4 generalizability to community physicians, and
5 perhaps for someone like me who is not in the
6 field of bariatric medicine or surgery, perhaps
7 somebody could give some background on who is
8 doing bariatric surgery today in the United
9 States, what is the training now being used and
10 what should the training be. I presume a lot of
11 this training is in general surgery residencies,
12 there may be some fellowships involved. If
13 somebody could give some general background, I
14 think that would be useful.

15 DR. PORIES: We have a spectrum, I will
16 just make a brief comment, because actually
17 Dr. Buchwald has better information about that
18 because he did a survey. But initially of course,
19 most of us were self trained. Then there was a
20 series of courses. But I think the standard today
21 is either a mini-residency of about three months,
22 but most of the new young people are now being
23 trained in fellowships, and the number of these
24 fellowships, the American College is very
25 interested in developing standards for these

1 fellowships just as we have for residencies. But
2 Dr. Buchwald has the actual data on who's doing
3 what.

4 DR. BUCHWALD: I could comment on that.
5 At the moment, over 73 percent of American
6 teaching programs, residency programs, and about
7 89 percent of fellowship programs are teaching
8 bariatric surgery.

9 DR. DAVIS: Yes.

10 DR. ABECAASSIS: I guess we've had
11 representatives of three different groups talk
12 about this issue and it does apply to this
13 question about how generalizable the procedure
14 might be in the community, and I'm just wondering
15 if the American Society of Bariatric Surgery and
16 the SRC and the American College of Surgeons are
17 working together on this, because I'm not sure
18 that I understand, and it may help my thought
19 process to understand how these groups are working
20 together to answer the question that you've just
21 asked.

22 DR. FISCHER: I think I can shed some
23 light on some of the things that have gone on and
24 they are very much in flux. Recently there was an
25 attempt by the Society of Surgery of the

1 Alimentary Tract, of which I was chairman of the
2 board at that time, and SAGES, which is the
3 Society of American Gastroendoscopic Surgeons, and
4 then some other groups to develop a fellowship
5 which would follow residency.

6 For various reasons there was a group
7 that put together some fairly rigid standards and
8 then the splinter groups went off and did
9 something on their own which unfortunately
10 sabotaged it. I think to a certain extent,
11 although there is a match, my guess is the
12 American Board of Surgery, of which I was chairman
13 about five or six years ago, will be taking over
14 all of these areas very much as they've had
15 sub-boards in pediatric surgery, vascular surgery,
16 and finally that will come under the American
17 Board of Medical Specialties and the ACGME, the
18 Accreditation Council for Graduate Medical
19 Education.

20 The College will be doing verification
21 of bariatric programs as part of its verification
22 process in which there is long experience. This
23 is now a quite large division of the College, the
24 Division of Research and Optimal Patient Care.
25 We've done -- and in general when we do

1 verification processes we do this in collaboration
2 and cooperation with other groups.

3 For example, the College now does the
4 Level I, Level II, Level III verification of
5 trauma centers throughout the country. These are
6 recognized by the state emergency systems. We do
7 that in conjunction with the American Association
8 of Studied Trauma. The cancer programs in various
9 hospitals are also verified by the College and we
10 do that in cooperation with the American Cancer
11 Society.

12 The Division of Research and Optimal
13 Patient Care has large programs in quality and
14 safety, team training, evidence-based surgery, and
15 for your information, we do very much support
16 improved performance and have programs and so in
17 this area we would welcome working with a whole
18 variety of different groups, bariatric surgeons,
19 whatever organizations they wish, SAGES, the
20 Society of American Gastroenterologic Surgeons,
21 the SSAT, and we've had informal discussions on
22 this issue with the ACGME and with the American
23 Board of Surgery.

24 So there are, it's a long-winded answer
25 to a very simple question. Yes, there are

1 fellowships. Are the fellowships standardized,
2 probably not. Will they be standardized in the
3 future, probably. And there are a number of
4 organizations working on that.

5 DR. DAVIS: Dr. Phurroughs?

6 DR. PHURROUGH: Dr. Fischer, let me ask
7 this as the CMS person here. If CMS were to
8 readdress its policy on bariatric surgery, then
9 would the College be supportive of our restricting
10 this surgery to facilities that went through some
11 kind of accreditation process that certified that
12 the physicians were competent and that the
13 hospital had some program that insured quality
14 outcomes?

15 DR. FISCHER: I can't answer on behalf
16 of the College because that would have to be
17 discussed starting with the committee and going
18 through the board of regents and all of that. But
19 my guess is that the College would like to work
20 with CMS in an effort, and all other interested
21 people to develop guidelines for quality and
22 safety, and we really would like to track patient
23 outcomes. I think I can say that. How it would
24 happen, how long it would take, I don't know.

25 DR. DAVIS: Dr. O'Connell.

1 DR. O'CONNELL: Perhaps Dr. Fischer
2 would, maybe I can put this question to you. In
3 the data that has been presented, the morbidity
4 rates seem to have been, they are fairly
5 acceptable on the low range, some have been high.
6 That is in dramatic distinction to what I'm
7 experiencing in clinical practice where I get a
8 chance to look at complications of morbid obesity
9 surgery. What I'm finding is patients who have
10 complications are, first, not admitted to the same
11 hospital where they had their morbid obesity
12 surgery, and the complications are then classified
13 in terms of the medical diagnosis, so you never
14 know the complications of morbid obesity surgery
15 because you can't capture all the data. And my
16 question is, how reliable is that morbidity data
17 that we're hearing today?

18 DR. FISCHER: I don't know the answer
19 to that but I can tell you the experience at our
20 hospital. At Beth Israel Deaconess we now have a
21 database of every single patient that's ever been
22 operated on, and we track that actively. And the
23 purpose of the database is to say okay, who got
24 readmitted, who had a complication, who had a
25 death that wasn't reported at the mortality and

1 morbidity conference.

2 I'm sad to say that there were a number
3 of such events that have happened, and this is in
4 all surgery, this is, you know, we do about 28,000
5 operations a year. So my, as chair of the
6 department what I have said is I want every single
7 complication which is increasing length of stay,
8 reported at mortality and morbidity conference,
9 every return to the operating room, you know,
10 every readmission within 30 days reported.
11 They're not.

12 Now, it depends on how you set up the
13 study. If you set up the study with an
14 independent nurse practitioner or somebody like
15 that tracking the patients as the College is now
16 doing in a hundred beta sites with NSQIP, you're
17 likely to get reasonable data. The other way, I
18 don't know.

19 DR. O'CONNELL: Do you pick up data
20 from other institutions?

21 DR. FISCHER: We try, yeah.

22 DR. DAVIS: Dr. Weiner?

23 DR. HESS: Could I speak?

24 DR. DAVIS: Yeah, and introduce
25 yourself.

1 DR. HESS: I'm Dr. Hess, in private
2 practice. I wanted to speak to this bariatric
3 surgery situation. Any good general surgeon
4 should be able to do bariatric surgery, the
5 problem is not are you technically able to do the
6 surgery. The problem is, are you able to
7 recognize complications and do you see your
8 patients afterwards frequently? Many times
9 patients are sent home one or two, or even three
10 days, four days after surgery, to come into the
11 office in two or three weeks. I want to tell you
12 that some of the worse complications occur after a
13 week or so, and if they are out in the country and
14 if they end up in another hospital, as was
15 mentioned here before, this poor person is in
16 trouble. And it happens over and over again and
17 these are the things that we need to put our focus
18 on. I don't think it's so important about the
19 technical part; every general surgeon should be
20 technically able to do this operation, but not
21 everybody knows or understands. Now after they
22 have a few deaths in the early time, they get a
23 little smarter and worried, but unfortunately, you
24 shouldn't have to have someone die to learn. You
25 ought to remember, Harry Truman said one time, the

1 only thing that's new is the history you haven't
2 read, and we're not teaching these things, and
3 they don't occur in other things anymore like they
4 used to. Thank you.

5 DR. DAVIS: Dr. Weiner.

6 DR. WEINER: I have a slightly
7 different line of questioning for the two
8 nonsurgeons that spoke with us as part of a larger
9 organization, specifically Dr. Stiles from Kaiser
10 and Dr. Still from Geisinger, both internists.
11 Although we're focusing on the surgery, part of
12 maximizing the benefit is getting the right
13 people, you know, avoiding type one or type two
14 error, that is, people that need a surgery get it,
15 and people who don't need the surgery don't get
16 it.

17 From your experience, again, as primary
18 care physicians working closely with surgeons,
19 what payers out there have gotten it right in
20 terms of criteria, particularly morbidities, BMI,
21 you know, based on the evidence and based on your
22 experience, would you like to recommend to us?

23 DR. STILL: Well, in central
24 Pennsylvania there is a whole host of different
25 insurers with differing criteria. I think that I

1 will just say the most common ones are a body mass
2 index of 40 alone without any comorbid medical
3 problems, or between 35 and 40 with comorbid
4 medical problems. Initially when we started our
5 program, our own health plan only reimbursed for a
6 BMI of 45 and higher with two uncontrolled medical
7 problems. I think that was too high for a new
8 program starting out, as we've talked about today,
9 so I think the NIH guidelines, I think from a risk
10 stratification from internal medicine is
11 appropriate, for a BMI of 40.

12 I would just like to comment with
13 regards to ACGME with regards to the care of these
14 bariatric patients. We do have a bariatric
15 medicine fellowship for internists for special
16 training in bariatric medicine. It is nonfunded,
17 a non-ACGME-funded fellowship. And I think like
18 the fellowships for minimally invasive surgery or
19 bariatric surgery, bariatric medicine fellowships
20 may be a great asset to come together to pull the
21 centers of excellence together.

22 DR. WEINER: And more comments? I'm
23 fairly convinced if you get good surgeons out
24 there, they will find people to do the surgery on.
25 But the issue of, as internists, if you can

1 comment on trying to see that only the right
2 patients are directed toward the surgeons. Again,
3 do you believe the criteria that you've expressed
4 will do that?

5 DR. STILES: As I see it, I'm a family
6 practitioner, is what I look at, I look at all
7 people who come for a potential surgery, and we
8 look at that them to make sure that they are, my
9 wording is, are you safe for surgery. We give
10 orientations to approximately a hundred patients
11 every month in small groups and we spend a whole
12 day doing that. At that time I give a pre-lecture
13 on what I mean by safety, because especially in a
14 managed care organization, so many people come in
15 feeling like they deserve the surgery, and indeed
16 they do, but I really feel that a safe patient is
17 the one we need to operate on, and I can say that
18 makes you have far less problems during the
19 surgery and after surgery.

20 And then what we do after that is we
21 make sure that that happens. I do, as I said in
22 my study, we look at the evidence and we look at
23 what the comorbidities are that could get our
24 patients in trouble, and we do every single thing
25 possible with many studies throughout our 30-plus

1 facilities in northern California to make sure
2 that the patients are safe.

3 And furthermore, the safety really has
4 to do with what you do with them afterwards, as my
5 distinguished colleagues have said. I think one
6 of my jobs at Kaiser is to meet with primary care
7 doctors throughout northern California to make
8 sure we have standards of care, to make sure that
9 not only are they followed at our center, which
10 they are able to be followed at all the time, but
11 also that doctors in the emergency rooms in the
12 primary care facilities have constant
13 communication with us so that when something is a
14 complication, they understand whether it's a
15 complication of the bariatric surgery, and I think
16 that's something that we're allowed to do.

17 DR. FISCHER: Could I just address your
18 question, just telling you how we reorganized our
19 bariatric surgery program, which is a big program.
20 In the newest program, in which we invited about
21 four internists to join the obesity center, every
22 patient who comes in will come in on the medical
23 side, and they will have the usual counseling and
24 interviews, so they will go for medical therapy
25 for six months and then if they don't make it in

1 six months they're referred for surgery.

2 We also have a tie-in with Jeff Flyer,
3 who's probably the leading basic scientist in
4 obesity in bench research and clinical studies.

5 DR. WEINER: Is that part of the
6 criteria of the certification we heard about, or
7 is that just what you folks do on your own?

8 DR. FISCHER: I don't know that it is
9 yet, but I really think you have hit the nail on
10 the head. There probably is a subset of people
11 that can -- don't forget, we're next to the Joslin
12 Diabetic Center and half of the patients we
13 operate on are diabetics, so there is a strong
14 tie-in between the two.

15 DR. ALLEN: Jeff Allen, University of
16 Louisville. I'd just like to comment briefly on
17 the question about the right people getting the
18 operation and the wrong people not getting the
19 operation. There are basic NIH criteria, BMI of
20 40 or above, BMI of 35 and above with
21 comorbidities. That's very arbitrary. There are
22 certainly people outside that realm that will
23 benefit. For instance, there are studies being
24 done in Australia, BMI 30 to 35 and diabetics,
25 where a small amount of weight loss compared to

1 the 400 or 500-pounders can make a significant
2 difference.

3 I think it's a fundamental
4 philosophical question where if you believe that
5 obesity is a disease, and I do, and if you believe
6 that you have the treatment, which I think we do
7 in some form of surgery, then it seems unethical
8 to withhold it from patients who will benefit from
9 that. And like I said, the BMI 40 is an arbitrary
10 thing. Consider a schizophrenic patient, and I've
11 operated on schizophrenic patients. We send
12 people to -- many people will send patients to a
13 psychologist to screen them, but would you
14 withhold treatment from a schizophrenic patient
15 who has an abdominal aneurism or somebody who has
16 cancer, or would you withhold it from a patient
17 who is 17 for a lap band because it's FDA off
18 label?

19 So I think perhaps the answer is
20 perhaps more in outcomes, and as bariatric
21 surgeons we have to better define who will
22 benefit, but I think it's important to bear in
23 mind that the BMI of 40 or above, or 35 to 40 with
24 comorbidities is very arbitrary and there are
25 certainly people outside that population who will

1 benefit.

2 DR. DAVIS: We're going to take one
3 more question -- well, go ahead and respond to
4 that.

5 DR. FISHER: Barry Fisher. I just want
6 to comment on trying to identify which patients
7 will benefit and which will not. There have been
8 several studies that have looked at preoperative
9 predictors of poor outcomes, and none have come up
10 with any conclusions. As I look retrospectively
11 at my own practice, the only thing I can find is
12 that patients who do poorly are patients who don't
13 comply. And so the only criteria we've applied in
14 our practice is patients who have a history of
15 poor compliance with medication for treatment of
16 medical conditions, we don't operate on. Other
17 than that, I would second what has already been
18 said.

19 DR. DAVIS: We'll take one more
20 question, Dr. Klein was going to ask a question,
21 and then we'll get an answer to that and then
22 we'll proceed with the other public presenters.

23 DR. KLEIN: This is regarding the
24 elderly issue specifically, and I think it should
25 be addressed to maybe Dr. Flum and possibly

1 Dr. Wolfe as well. A lot was said about age
2 increasing your risk of complications and
3 mortality after surgery, which is true of all
4 operations, and I know there's very little data,
5 but could you review for us specifically the data
6 that's available regarding the actual complication
7 rates, mortality rates in older people 65 or
8 older, versus younger people having this
9 operation, and how that compares to older and
10 younger people having other operations like colon
11 cancer surgery or whatever is a similar type of
12 morbid complication?

13 DR. FLUM: I'll start with some of the
14 observational studies that are out there which we
15 know of. Dr. Sugarman reported zero mortality in
16 a cohort of patients over the age of 65 having a
17 gastric bypass. We know in data from our own
18 state, we clipped the cohort at 65 because of an a
19 priori definition of what older was. But as you
20 get to 60, 61, 62, 63, we see the mortality rate
21 creeping up and creeping up higher than that 2
22 percent rate we talked about. Now that parallels
23 very nicely to colorectal operations or the data
24 on hip arthroplasties.

25 The real question here, and this now

1 broaches the last question, is the question of
2 risk and reward. As you get older, the rewards
3 shift from survival extension to quality of life
4 and comorbidity improvement, and so that data is
5 wholly unavailable.

6 DR. WOLFE: Bruce Wolfe. The data that
7 the risk, mortality risk of obesity diminishes
8 with advancing age is not new, so we have been
9 aware of that for many years. It's been intuitive
10 that operative risk would rise with advancing age,
11 and now there is data to support that. Those two
12 facts taken together have led many of us who have
13 been doing bariatric surgery for many years to
14 discourage patients from undergoing surgery, so
15 the total number of patients over 65 who have
16 actually undergone bariatric operations is
17 obviously very small, and that is presumably the
18 reason that there aren't more data published on
19 the subject, there haven't been very many done.

20 In the public comment, the details of
21 the Medicare experience and just what, who are the
22 people covered by Medicare that have undergone
23 bariatric surgery, in essence shows that 80 to 90
24 percent over the last three years have not been 65
25 years of age, so the vast majority of Medicare

1 beneficiaries have been in the disabled group who
2 are not qualified for Medicare on the basis of
3 age, so the total number of subjects to analyze is
4 not very great.

5 It's a reasonable hypothesis to pursue
6 and hopefully the expanded database that the NIH
7 consortium will address will be large enough to
8 address the issue more specifically, but we as
9 individual surgeons have to be cautious when we
10 see a patient that is over 65 in presenting the
11 outcomes data to them.

12 DR. DAVIS: Thank you. I hope most of
13 the presenters or all of them will be able to stay
14 until our afternoon session, because I'm sure the
15 committee members would like to continue this
16 dialogue, but in order to squeeze in the other
17 public presenters before the lunch break, let's
18 move to them now.

19 The first on the list is Morgan Downey.
20 And again, we will try to limit these, we will
21 limit these to three or four minutes and again,
22 ask the presenters to indicate any financial
23 conflict of interest and how they had their way
24 funded to come.

25 MR. DOWNEY: I'm going to withdraw. I

1 don't think I have anything to add at this point.

2 DR. DAVIS: Thanks for being with us.

3 Monica Ganz.

4 MS. GANZ: Good morning. Thank you all
5 for allowing me to be here and addressing the
6 panel and committee and everyone else. My name is
7 Monica Ganz and I am from Woodland Hills,
8 California and I represent Obesity Help, Inc.,
9 which is a supportive and resource group for
10 morbidly obese people. We are on line face to
11 face and we provide a place for morbidly obese
12 people to come and get answers, information,
13 resources, friendship, support and help.

14 I'm here to represent over a quarter of
15 a million of our members who are all morbidly
16 obese or who have gone through some form of weight
17 loss surgery, myself included. This is me just
18 three years ago, less than three years ago. It's
19 a visual. I'm a visual teacher. I weighed over
20 450 pounds at the time and I'm only five-two. I
21 could not walk or function as a normal human
22 being, and as Dr. Wadden spoke of the psychosocial
23 issues, I was a victim of all of those, ridicule,
24 discrimination, I just wanted to be normal again.
25 I had no other options. I suffered from sleep

1 apnea. Diabetes, my triglycerides were at 788.
2 My cholesterol was at 358. And to say I was a
3 walking time bomb was just, I couldn't walk, so
4 that couldn't even be.

5 On January 14th, 2002, Dr. Edward
6 Livingston saved my life by performing a Roux-en-Y
7 gastric bypass at UCLA. Within one year, all my
8 blood levels were back to normal, I'm no longer on
9 the sleep apnea machine or CPAP. I went from
10 being a nonproductive member of society to being a
11 participating member of it again. If I had not
12 been married, I would have been unemployed and on
13 disability and a Medicare recipient myself. I am
14 now down 266 pounds, paying taxes and supporting
15 the system instead of living off of the system.

16 Obesity Help has approximately 4,800
17 members on Medicare, and that's what's in that
18 box, a message to you from each of them. They are
19 all concerned about what is being decided here and
20 they wanted their voices to be heard. Of that,
21 255 of them are 65 years or older, which is about
22 5.3 percent, but let me say by being morbidly
23 obese and being 65 and over is an oxymoron, as
24 anyone who is morbidly obese doesn't have much
25 chance of hitting 65.

1 And as many of the doctors and surgeons
2 can confirm, as they did in some of the talks
3 earlier, not only does the surgery need to be
4 covered, but the support system pre and afterwards
5 needs to be covered. In my travels because I set
6 up support groups for Obesity Help, I talk to the
7 patients all the time, pre and post, and the most
8 successful ones are the ones that are in a
9 supportive environment continually for years
10 afterwards. We are no different than the
11 alcoholic or the drug addiction, we just have a
12 food addiction, and we continually need to be
13 surrounded by people that understand what we are
14 going through and battle those issues day to day.

15 We ask that Medicare makes an educated
16 and timely decision, and listen to the many silent
17 morbidly obese people that I brought their voices
18 with me in a box. I again thank you all for
19 listening and making an educated decision.

20 DR. DAVIS: Thank you. Dr. William
21 Denman, if I'm reading this correctly.

22 DR. DENMAN: Good morning, and thank
23 you very much for having us be able to testify to
24 you. I actually have two hats. I am the medical
25 director for Tyco Health Care, but I'm also a

1 practicing anesthesiologist with a subspecialty in
2 pediatrics. So to all my surgical colleagues, I
3 want you to know that we are on the same side and
4 there is an alignment here.

5 I would like to just address something
6 to the panel not completely about morbid obesity
7 surgery but about the things that we deal with in
8 those patients who are morbidly obese who haven't
9 had the weight loss procedure. Those of us who
10 teach anesthesia certainly inform and try to
11 impose upon our residents the issues that they're
12 going to face when they're dealing with patients
13 who are obese and particularly morbidly obese.
14 Things that we deal with are positioning; it's
15 very very hard to position patients who are
16 morbidly obese or very heavy. The number of times
17 that we put to sleep and have to deal with
18 patients who are not coming for bypass surgery but
19 are morbidly obese and having other types of
20 surgery is obviously exploding at the moment.

21 Tremendous trouble with pulmonary
22 function. Postoperatively I run a pain service in
23 my hospital to try to deal with patients who are
24 morbidly obese who can't breathe who have
25 pulmonary dysfunction, and trying to manage their

1 pain acutely and chronically is incredibly
2 difficult.

3 Cardiovascular problems obviously,
4 hypertension and all the issues that we see here
5 that we deal with in the morbidly obese are
6 present in the patients that are obese coming for
7 other types of surgery. Aspiration, difficult
8 airways, et cetera.

9 So, I guess the point I'm trying to get
10 across here is for those of us who are dealing
11 with morbidly obese patients who are not coming
12 for morbidly obese surgery, and the wonderful
13 thing about those patients is if we're dealing
14 with all those issues, is that there's light at
15 the end of the tunnel for them. What I would
16 suggest and what I would hope that we would
17 continue to do and obviously I wear two hats, so I
18 want everyone to understand that, is that as I see
19 an explosion in the comorbidities that we're
20 facing in the rest of my surgical patients that I
21 deal with, the thought of being able to decrease
22 that and to decrease the number of operations we
23 may be dealing with because of morbid obesity is
24 obviously something that this side of the
25 blood-brain barrier is very keen on. Thank you

1 very much.

2 DR. DAVIS: Any conflicts of interest?

3 DR. DENHAM: I'm hoping Tyco is going
4 to pay my way, but obviously yes, my travel and my
5 appearance here is based on the fact that I am the
6 medical director for Tyco Health Care.

7 DR. DAVIS: Thank you. Henry Alder.

8 MR. ALDER: Good morning. My name is
9 Henry Alder, I am with Ethicon Endosurgery, a
10 Johnson & Johnson Company. In terms of conflict
11 of interest, Ethicon Endosurgery, J&J will be
12 paying my way.

13 I wanted to just add some perspective
14 to question number five on the questions, the
15 Medicare population aged 65-plus. We took the
16 liberty of looking at the MedPAR data, which is
17 CMS's own Medicare database, and looked at the
18 prevalence of bariatric gastric bypass surgery
19 under ICD 944.31 to look at the number of
20 procedures. In 2001, there were a total of 2,250
21 procedures done on the Medicare population. That
22 increased to 3,603 in 2002, and then up to 5,438
23 in 2003. But within the that population of
24 Medicare patients, going back to 2001, only 8
25 percent were over the age of 65, greater or equal

1 to age 64, that is 177 patients. In 2002, 329
2 patients were greater or equal to 65, which made
3 up 9 percent of the Medicare population. And in
4 2003, the total Medicare population over 65 was
5 672, or 12 percent. So that would probably
6 suggest that the Medicare population that is
7 benefitting, again, just from this one procedure,
8 gastric bypass, is probably going to be the
9 disabled or potentially those who are suffering
10 from kidney disease. I thank you very much for
11 your time and appreciate it.

12 DR. SUGERMAN: Henry, do you have the
13 mortality data, I think it was already alluded to,
14 in that MedPAR?

15 MR. ALDER: I had the mortality data
16 but I didn't make it available for public comments
17 today.

18 DR. DAVIS: Is it Mike Christeau?
19 Nick, sorry about that.

20 DR. CHRISTIAN: I'm Nick Christeau,
21 professor of surgery at McGill University in
22 Montreal, Canada, I am director of the bariatric
23 surgery program up there. You've heard people
24 mention my name here today and I rise to clarify,
25 because we were limited somewhat this morning, to

1 clarify a little bit the issue of comorbidity and
2 whether, because you have two of these sheets that
3 you have to vote on and you heard a lot of my
4 colleagues say this morning that the data on
5 patients without comorbidity really doesn't exist
6 because there are not that many people who don't
7 have comorbidities.

8 In our particular study, which you
9 heard parts about, on over a thousand patients
10 that underwent bariatric surgery at our center
11 compared to about 5,000 controls drawn from the
12 administrative database of the province of Quebec,
13 what I would like to point out is that this
14 particular database is a single payer system.
15 Therefore, anybody that dies in the province of
16 Quebec, some physician has to fill out a death
17 certificate and charge them the \$12.50 fee that
18 he's entitled. Therefore, we capture all
19 treatments, mortalities, hospitalizations,
20 physician visits, prescription medications, and it
21 gives us an indirect access to the comorbidities.

22 So when we show that surgery reduces
23 the cancer visits for example, what we did with
24 the study is we excluded for the six months prior
25 to the entry in the study those who had already

1 seen a physician or had gone to a hospital for
2 either a cancer-related diagnosis, infectious
3 disease, or musculoskeletal. And even though it's
4 not perfect and clean and pure prospective
5 randomized trial, it does indicate that at least
6 for the six months prior to entering the study,
7 those people were not going to the hospital using
8 up health care for these conditions, but
9 afterwards there were marked differences between
10 the two groups.

11 Therefore, one can infer from this
12 data, and I know the statisticians in the group
13 may not like this, but one can infer that even if
14 you do not have comorbidities, over a five-year
15 follow-up with this particular study, the people
16 that did not have the operation in the red have
17 much higher incidence of these comorbidities as
18 reflected by them going to see a physician or
19 being hospitalized for their treatment. The same
20 thing goes for respiratory and mental disorders.
21 And the digestive disorders being higher serves as
22 an internal consistency control of our data.

23 Now prior to coming down here, I
24 reviewed our own database which has been kept
25 since 1964, our registry in paper form, and then

1 switched to electronic in 1995, and now we can
2 search it effectively. And unfortunately for us,
3 even though Medicare covers this procedure, we do
4 not get paid by the patient, there is a global
5 budget and within the global budget I have to
6 fight with the cardiac surgeons and with the
7 orthopedic surgeons for resources to perform these
8 surgeries. Therefore, the waiting list is up to
9 five years. My own personal waiting list right
10 now from the time somebody calls the office until
11 going in for surgery is about 5.2 years, and up in
12 Quebec City it is the same thing.

13 And I queried our database and we have
14 had three deaths within people waiting for that
15 period. One was a lung cancer that obviously
16 caused the patient's death, one was a patient from
17 a cardiovascular event, and one was a suicide from
18 a mental disorder, and I think we're
19 underestimating the mental disorders that you see
20 here.

21 The other good thing that came from
22 this study is that since the number of
23 hospitalizations and hospital days and physician
24 visits were markedly decreased in the bariatric
25 cohort, this translates to a very nice argument

1 that I could certainly make with our single payer
2 system, and I think would apply to Medicare here.
3 And that is, if the Minister of Health tomorrow in
4 the province of Quebec, or in Ottawa more
5 centrally, were to invest \$8,500 Canadian for a
6 patient to undergo this bariatric surgical
7 procedure at times zero, and that gives us the
8 first year that you see here on the left. And
9 then we accrue the cost savings.

10 Mr. Willis indicated how much he who
11 was paying for his medications. This is hard
12 proof that indeed, there are cost savings. After
13 about 3.2 years the color changes because now the
14 ministry actually saves money, or the single payer
15 system saves money by investing that \$8,500 at
16 times zero to have the patient operated, to have
17 them look at some of the patients that we saw
18 today. Thank you very much for your attention.
19 I'd be happy to answer additional questions in the
20 afternoon on this subject.

21 DR. DAVIS: Thank you. John Kral.

22 DR. KRAL: I'm John Kral, I'm a
23 professor of surgery at SUNY Downstate in New
24 York. I am employed by New York State and by New
25 York City. Throughout my career since 1970 when I

1 started operating on people with obesity, I have
2 been an employee of university hospitals. I've
3 never derived any financial benefit, nor has my
4 employment even been dependent upon my operating
5 on obese people. You will not hear a commercial.
6 I paid for my own trip.

7 The reason I am here is not to extend,
8 and certainly not to stand between you and lunch,
9 it's not to extend the tutorial that you have been
10 subjected to this morning, I think everybody has
11 done their best. I'm here to express my concern
12 over some of the issues that you will of course,
13 that are possibly clouding your interpretation of
14 data and how you look at what has been presented
15 today.

16 I think you have been perfectly
17 apprised of the fact that you can tear up the
18 sheet that says, that provides the questions about
19 with no comorbidities, I think that has been made
20 abundantly clear, that that's an unnecessary
21 exercise to even consider that in people 65 or
22 older, or those younger in Medicare who are
23 already disabled.

24 As far as quality of data, though, I
25 want to address that a little bit too. I do hope

1 that you have understood also that the standard,
2 the human cry to see, as with drug studies,
3 prospective randomized controlled trials is
4 neither ethical, scientific, nor even feasible to
5 perform. Not to cloud the issue of approach, I'm
6 going to make a rather strong statement. If you
7 were to have a show of hands here amongst the
8 surgeons, let's do the following little
9 experiment. Let's assume that the surgeons, that
10 some of the surgeons here are severely obese and
11 need an operation. I'd like for you to ask for a
12 show of hands whether they would like the surgeon
13 who's doing the approach laparoscopic who's done a
14 thousand laparoscopic approaches, or to be
15 randomized between that and having a surgeon who
16 has done a thousand open approaches do their
17 surgery. I would imagine that nobody would be
18 asking in the year 2004, 2005, to have their
19 surgery done openly, everything else equal.

20 Now, as far as publication bias is
21 concerned, and that's something that you have to
22 be concerned about, having heard so many
23 advertisements here this morning, I think
24 Dr. Christeau has the type of evidence and the
25 type of material that is rather free from that. I

1 think the efforts being made by the Surgical
2 Review Company, you heard Dr. Pories present the
3 efforts that are being made, and Dr. Fischer from
4 the American College of Surgeons. Registries and
5 capturing is a good thing.

6 The experience from Canada, and I have
7 personal experience from Sweden, where there is
8 virtually no non-government paid surgery performed
9 for obesity, all patients are there being
10 captured, there is virtually no private sector
11 there at all. You can trust that kind of data
12 when it comes to outcome evaluation, and not fear
13 the publication bias that you're always going to
14 have when people are advertising their wares.
15 Thank you for the opportunity to be heard.

16 DR. DAVIS: Thank you. Dr. George
17 Cowan. He's the one who stands between us and
18 lunch.

19 DR. COWAN: Yes, I'm standing indeed.
20 I thank you very much for the opportunity to
21 stand. I am past president of the American
22 Society for Bariatric Surgery, founder and past
23 president of the International Federation of
24 Surgery for Obesity, co-founder of the Journal of
25 Obesity Surgery, and a few other things. More

1 importantly, I became professor emeritus, got my
2 honorable discharge at the University of Tennessee
3 at age 66 this year, so I am free at last.

4 However, I am currently very minimally part-time
5 employed by Specialty Health Services, and I hope
6 they will pay a little bit of my trip here.

7 I have three main points. One is as we
8 heard, the vast majority of individuals receiving
9 Medicare coverage are disabled, they are not over
10 65, so the age thing is relatively irrelevant
11 right now, although we may be in the future
12 looking at that because we hope more individuals
13 if they survive that long, may indeed have the
14 privilege of the surgery. My father died at 60,
15 never got that far, morbidly obese.

16 The average age is about 50 years.
17 After the surgery, about a year later, the
18 majority return to the work force, they return to
19 the work force and two major things happen. One,
20 they are no longer receiving money from the
21 government on the dole to support them because
22 they're disabled, and they in turn are making a
23 salary and paying taxes to the government to
24 support others who are disabled. It's a double
25 benefit.

1 The study from Sweden in our first
2 issue of Obesity Surgery 14 years ago showed
3 clearly that in three years those who had the
4 bariatric surgery paid sufficient taxes to recover
5 the cost of the bariatric surgery, isn't that
6 amazing, and you have 12 more years to go until
7 you reach Medicare age in that sense if you're
8 looking at the numbers. So there is a dramatic
9 turnaround of not paying money for support for the
10 disability, and people paying taxes in addition
11 who are supporting others, it's a double benefit
12 of the surgery.

13 Look at also at the competitive
14 surgeries for the limited dollars of Medicare or
15 limited support. It is competing with CABGs, it
16 is competing with hip surgery, average age 70.
17 These people do not return to the work force.
18 They are in better shape to the love of their
19 family and their grandchildren and such like, but
20 they don't have that additional 15 years of
21 actually paying taxes, the opportunity to pay
22 taxes, the opportunity to make a living and come
23 off the dole. And this is very important if
24 you're looking at the limited slice. I'm not
25 saying to withdraw CABGs or to limit them for

1 Medicare, but I'm just saying if you're looking at
2 the benefits of bariatric surgery, it's way up
3 there, it's the best bargain that Medicare has and
4 offers, that it gets back to the American
5 taxpayer.

6 Secondly, the comorbidities, I agree
7 with Dr. Kral, that's basically in the tank from
8 the point of view that most Medicare individuals
9 that are disabled and are disabled by the
10 comorbidities, therefore why are we worried about
11 comorbidities versus none when somebody is
12 morbidly obese. However, those few percent that
13 I've maintained in my experience of 4,000
14 bariatric surgeries, that the people who have no
15 true comorbidities are those in the ages of about
16 16 to about 25. They have psychosocial
17 comorbidities of sorts, but physically they are
18 pretty limited, I will agree. However, that's not
19 what we're dealing with or talking about today,
20 but those same 16-to-25-year olds, give them five
21 or ten years and they're all going to have
22 comorbidities, they're there. And therefore this
23 is a non-issue, because I ask the panel to look at
24 the potential for development of comorbidities,
25 what is the percentage of development of

1 comorbidities? It's 95 to 98 percent. Why?
2 Because these individuals will not succeed with
3 voluntarily weight loss, they are failures. And
4 when they fail, they get bigger and bigger and
5 bigger after perhaps having lost vast amounts of
6 weight, but they get bigger, develop the
7 comorbidities, and then the potential for
8 comorbidities is important to consider the same as
9 comorbidities, it's virtually 100 percent of those
10 who come to surgery.

11 Third, we should indeed with Medicare
12 insist on standards. Should we insist on a
13 particular purveyor of standards who says you are
14 okay, you are not? I don't know that Medicare
15 really wants to go that far, but I would suggest
16 that there's an excellent set of standards that
17 have come through the American College of Surgeons
18 that Dr. Buchwald has helped to write from the
19 American Society for Bariatric Surgery, and these
20 are also in part some of the basis for the SRC
21 standards, which I would certainly ask the
22 panelists to look at from the point of view of
23 valuable standards themselves, not necessarily the
24 organizations, but the standards, although the
25 organization is pretty good too, but the standards

1 are something to look at and certainly could be
2 made available.

3 Last, I would like to give you
4 something some of you might see as humorous.
5 People have called obesity a political disease,
6 morbid obesity a political disease. You can argue
7 about that. You can't argue with the people who
8 have testified today that they were diseased and
9 that they were fat and they are smaller and they
10 are no longer diseased.

11 Now, nine out of ten of all the cases
12 of diabetes mellitus would not exist if we had no
13 obesity or overweight. Think about that. Which
14 is true? Is diabetes the disease or is obesity
15 the disease? I would maintain that in nine out of
16 ten of those individuals who are large, that
17 indeed diabetes mellitus type 2 is a secondary
18 condition to the disease of obesity. So maybe we
19 ought to downplay diabetes mellitus to a condition
20 and admit that obesity is the disease. Just a fun
21 think point, but thank you very much for the
22 opportunity. I am also the historian for the
23 American Society for Bariatric Surgery and I'm
24 looking forward to seeing the results of history
25 being made today and having the privilege to

1 report that for the future in some of our work.

2 Thank you.

3 DR. DAVIS: Thank you very much. A lot
4 of food for thought for the lunch hour. We'll
5 break for 60 minutes. It's ten after 12 on my
6 watch, so 1:10, we will reconvene.

7 (Luncheon recess.)

8 DR. DAVIS: I think we'll get started.
9 Some people might have gotten stuck in the
10 restaurant because they obviously weren't ready
11 for the large crowd given the bad weather outside,
12 but we're scheduled to go from now until 4:15 or
13 so, including discussion and voting. That's not
14 to say that we have to use up all of the time if
15 we don't need it, but we did have a lot of useful
16 dialogue and Q&A in the morning, and I think we
17 might as well just pick up where we left off
18 before lunch and open it up for questions from
19 committee members after Dr. Phurrough makes a
20 point.

21 DR. PHURROUGH: I would just like to
22 clarify CMS's current issues around bariatric
23 surgery. First of all, we are well aware that
24 there are very few Medicare beneficiaries over the
25 age of 65 who are currently getting this surgery,

1 we understand that. However, 90 percent of our
2 population falls into this over 65 age group, and
3 as the numbers Dr. Alder presented right before
4 lunch, even though those are small numbers, they
5 represent a 2 or 300 percent increase in the
6 number of patients who are getting this procedure
7 who are over the age of 65, and that number is
8 obviously going to grow as our population grows.
9 We add just about a million new beneficiaries
10 every year over the age of 65, that's the
11 population of our country that's reaching the age
12 of 65 annually, and there's going to be a spike in
13 that in the next couple of years.

14 So we're aware that it's not a big
15 issue currently in the 65-plus population, but if
16 we are in fact going to change our policy at all,
17 we obviously have to address whether we are going
18 to change that policy and how it affects the vast
19 majority of our population, those who are over age
20 65. And in fact, we may need to have different
21 policies based upon age or different indications
22 or different criteria based upon age. So that's
23 the reason why we want to know and we've asked the
24 question such that, what's the benefit of this
25 particular surgical procedure in the literature,

1 and then can you apply those results to the
2 65-plus population.

3 Secondly, there has been the question
4 of why are we asking about patients who don't have
5 comorbidities. Everybody who's morbidly obese has
6 comorbidities. Everybody who's over age 65 and
7 who's obese has comorbidities. Well, the reason
8 we're asking that question is we've been asked to
9 ask that question. The public is interested in
10 why we have a procedure limited to patients with
11 comorbidities when in fact patients who don't have
12 comorbidities might benefit. So because we
13 already have a decision around patients who have
14 comorbidities, we need to ask the question around
15 patients who don't have comorbidities, and if the
16 answer is those patients don't exist, that's fine.
17 Though, in spite of some of the comments we've
18 heard today, we have been concerned in reviewing
19 some of the literature that if you add up all the
20 comorbidities that are listed in the patient
21 populations in the trials, it doesn't end up being
22 the entire population that was treated in the
23 trial, so they are obviously either not asking the
24 question, not asking the question extensively
25 enough in identifying all the comorbidities, or

1 there are patients who don't have the
2 comorbidities. So, we think it's a legitimate
3 question even though the population may again, may
4 not exist.

5 Also, I just want to clarify, we
6 understand that our questions sometimes appear
7 outside current practice or outside current
8 populations in which we are providing
9 reimbursement, but they are in fact we think
10 appropriate questions based upon our current
11 policies and the potential to change that policy
12 in the future. So, I hope I have not confused
13 that more, I just wanted to clarify. We do
14 recognize some of the difficulties in the
15 questions.

16 DR. DAVIS: Dr. Weissberg had his hand
17 up.

18 DR. ABECAASSIS: I just wanted to
19 clarify the clarification.

20 DR. PHURROUGH: I must be a good
21 bureaucrat, I've confused you more.

22 DR. ABECAASSIS: I just have a very
23 specific question about the whole sheet on
24 patients without comorbidities, and one of the
25 questions asks how we expect these procedures to

1 affect comorbidities. In the patients that have
2 no comorbidities, am I to assume that that means
3 prevent comorbidities?

4 DR. PHURROUGH: Yes.

5 DR. DAVIS: Yeah, Bill.

6 DR. OWEN: I have a question and I
7 don't know if this is the appropriate time to pose
8 it.

9 DR. DAVIS: Yeah, go for it. That's
10 fine.

11 DR. OWEN: This has to do with the
12 issue of comorbidities. Unencumbered by any
13 knowledge, I was likewise impressed that there was
14 some sort of, I will presume ascertainment bias in
15 the papers that were submitted to us, because it's
16 exactly as you say, it doesn't add up to 100
17 percent of the patients that have comorbid
18 conditions. So my query is, does anyone here know
19 if there are any longitudinal cohort studies that
20 are ongoing of patients who have BMIs of 35 or
21 above, a natural history study, so that we know if
22 this is true, I have to take the data as it is,
23 and there are patients who are listed who don't
24 have any, so do we know if that group behaves like
25 an equivalent group that does not, or should I say

1 who does have it.

2 DR. DAVIS: Please. And if you could
3 mention your name again, that would help.

4 DR. KRAL: I'm John Kral, from
5 Downstate. The Swedish study is a longitudinal
6 study looking at the natural history of obesity,
7 and their inclusion criteria actually noted a body
8 mass index of 34.7, and that is ongoing for many
9 years and should be able to answer that query as
10 far as prognosis is concerned. That's probably
11 the best available data.

12 DR. SUGERMAN: Did it show that there
13 are progressive increases in the comorbidities,
14 all of them that are listed?

15 DR. KRAL: Yeah, there's a progressive
16 weight increase and there's a progressive
17 deterioration in all of the -- they develop
18 comorbidities that weren't there to begin with,
19 and the ones they have are aggravated, even though
20 they're trying to control them.

21 DR. OWEN: I'm aware of the ones who
22 already have coexisting disease worsening, but
23 they have a subgroup that they follow that we will
24 ultimately have access to that will have no
25 comorbidities that we can do a natural history on?

1 DR. KRAL: Yes, because the whole
2 population is captured and it's a national data
3 bank.

4 DR. MARGOLIS: There are also studies
5 ongoing in this country, NIH sponsored studies
6 usually looking at educational interventions or
7 medical therapies or individuals over time to see
8 how effective or ineffective they are. Although
9 they're not directly answering your question, they
10 are looking for those sorts of things, so that
11 either exists now or could exist as a secondary
12 analysis from those studies, and I'm aware of two
13 of them and I'm sure there's more.

14 There's studies usually sponsored by
15 NIDDK looking at long-term effects of educational
16 interventions in obese populations, some within
17 minority groups, some within the general
18 population, and they are usually looking at
19 interventions and weight loss, but certainly
20 they're looking for other illnesses as well and
21 those answers could be there. Now whether or not
22 there is morbidly obese, as some of the patients
23 we're talking about here, I don't the answer to
24 that, but I know they exist.

25 DR. DAVIS: I was interested in looking

1 a little more carefully at the Swedish study and
2 that's why I asked CMS staff if they could
3 distribute copies of the paper to you, which I
4 think they did earlier in the day, although you
5 don't have the complete article unfortunately, at
6 least my version only goes through page 6 of 16.
7 And of course the study was referenced in a lot of
8 the technology assessments that we have been
9 given, but one question I had about this ties into
10 the question that was just raised, and that is,
11 what happened with the control group in the
12 Swedish study? Were they subjected to any sort of
13 nonsurgical intervention? And the pages that we
14 have do reference at the beginning of the results
15 section that the control group was conventionally
16 treated, but I don't have any more information
17 than that. I don't know if anybody else has any
18 more information on what happened to the control
19 group in the Swedish study.

20 DR. PORIES: Dr. Kral can answer it
21 better than I can, but just very quickly, the most
22 disturbing evidence of what you want, Dr. Owen, is
23 what's happened with children. As we now see this
24 epidemic of adolescent obesity, we're now seeing
25 adult onset of type 2 diabetes and every one of

1 the complications coming on earlier, and I think
2 that shows that along with the obesity, this comes
3 with it.

4 DR. KRAL: John Kral. Medicine in
5 Sweden is subsidized, so it is not out-of-pocket
6 expenses. All the subjects who are entered into
7 this are receiving what is called conventional
8 treatment, meaning whatever is offered by their
9 general practitioners, and it includes anything
10 from diet, diet and exercise, behavioral, and
11 cohorts with drugs, so anything but surgery is
12 what they consider to be part of the control
13 group, and it is simply a community practice as it
14 is provided, and it is provided.

15 DR. DAVIS: Dr. Weissberg.

16 DR. WEISSBERG: Let's shake it up a
17 little bit after lunch here. The panel has to
18 make decisions about the different types of
19 surgery and we've heard a lot about the fact that
20 all of these variety of surgery can be done safely
21 and well. The question, though, is for this
22 increasing segment of the American population,
23 neither commercial or eventually Medicare, only a
24 tiny fraction of whom are currently accessing any
25 of these approaches, where should the locus of

1 control be for determining which patient gets
2 which operation? Should there be a web site that
3 helps the patient work through if there are
4 trade-offs between more gradual but continued
5 weight loss with lower risk of immediate
6 complications for a lap band, or more profound
7 weight loss for a duodenal switch at the expense
8 of a longer operating time and a higher number of
9 reoperations? Where are those decisions supposed
10 to get made, and are the centers of excellence
11 that we vaguely referred to going to be set up so
12 that different operations are all available in
13 each one of these centers?

14 DR. PORIES: My name is Pories and I'm
15 rising again, sorry. That's probably one of the
16 most fundamental reasons for setting up the
17 centers of excellence, is to develop a database on
18 standardized operations in well-described
19 patients, and then at the same time make sure that
20 these databases are coordinated with the ones from
21 the NIDDK lab study. And as you probably know,
22 we've just finished developing the databases for
23 the lap study, it took us about a year. So I
24 think you almost have to sort of look at these
25 operations in the same way we look at antibiotics.

1 There is no one ideal antibiotic for all
2 infections, there is no one ideal antidepressant,
3 and I don't think there is one ideal operation for
4 all patients.

5 DR. WEISSBERG: But an internist has
6 the option and the facility to prescribe one of 20
7 different antibiotics equally well. I get the
8 impression that surgeons specialize in their
9 procedure of choice.

10 DR. PORIES: I think in most centers
11 now, taking some time with some, certainly the
12 bands and the gastric bypasses aren't being
13 offered, the duodenal switch is coming in a little
14 bit more slowly but is also being considered. We
15 didn't feel in the centers that we could prescribe
16 what operations a surgeon should do, they have to
17 choose that themselves and then tell us exactly
18 what we're doing, and then promise to do it in a
19 standardized fashion long enough that we can
20 gather the data.

21 DR. DAVIS: Dr. Sugerman, you had your
22 hand up a few moments ago.

23 DR. SUGERMAN: I did, and I just want
24 to go over one more time some of the concerns that
25 have been mentioned here, not as a question but as

1 a statement. And again, I'm here on the panel but
2 I'm also the president of the American Society for
3 Bariatric Surgery. I think you have heard over
4 and over again that there is a really major
5 problem with the unequal distribution of coverage
6 for Medicare patients from region to region in the
7 country regarding both the types of eligible
8 comorbidities and the types of bariatric surgical
9 procedures, and whereas some places will support
10 this operation or that operation, it's variable.
11 And that surgeons in hospitals are performing the
12 procedure without a guarantee of reimbursement, so
13 there is a risk to operating on one of these
14 patients if you're not going to get paid for it.
15 And then each of cases requires additional
16 bureaucratic review of every case as to whether
17 there is an adequate comorbidity or not.

18 In terms of comorbidities, I like to
19 say that this disease starts at the top of the
20 head and ends up in the toes, and it hits every
21 single organ in between. And the problem with the
22 manuscripts is they don't look at every single
23 comorbidity. For example, Dr. Buchwald's paper in
24 JAMA looked at four. And you know, that's why you
25 don't see 100 percent comorbidities perhaps in

1 these manuscripts.

2 So from my point of view, it seems to
3 me that the Medicare system, and it would require
4 a new decision and coverage decision, should use
5 the 1991 NIH criteria. It would then increase
6 uniformity of access and assure surgeons and
7 hospitals of appropriate reimbursement and improve
8 bureaucratic efficiency. So, I'm just making it
9 as a statement and throwing it for discussion,
10 even though I know that's not the questions we're
11 being asked.

12 DR. DAVIS: I have Doctors McNeil, Raab
13 and Buchwald on my list. Barbara?

14 DR. MCNEIL: I'd like to ask Dr. Alder
15 a question. Is he still here? You mentioned
16 before lunch that you had done an analysis of the
17 MedPAR file and gave us the figures of the
18 increase in percentage of Medicare individuals
19 over 65 who were having bariatric surgery between
20 '01 and '03. And then somebody asked you a
21 question about the mortality results and you said
22 you didn't have them, you had them but you didn't
23 have them. Could you say a little more about
24 that?

25 MR. ALDER: Sure. First of all, it's

1 not Dr. Alder, it's Henry Alder.

2 DR. MCNEIL: Okay.

3 MR. ALDER: And we did have mortality
4 rates, but they were in the computer, so over
5 lunch I was able to download it, and I have
6 mortality rates for the Medicare population.

7 DR. MCNEIL: Oh, good. What are they?

8 MR. ALDER: This is for all Medicare,
9 and for 2001 was 1.2 percent; 2002, 0.9 percent;
10 and 2003, 0.8 percent. And this is for all
11 Medicare beneficiaries.

12 DR. WEINER: Over what period, one-year
13 mortality?

14 MR. ALDER: 30 days. Now we also have
15 average length of stay.

16 DR. MCNEIL: How about, though, for the
17 over 65, that was my real question.

18 MR. ALDER: We don't have it segregated
19 by age.

20 DR. MCNEIL: But you could, right?

21 MR. ALDER: It's evidently an
22 opportunity to do that, and going back to our
23 vendor to get that segregated, right.

24 DR. MCNEIL: Oh, a vendor did this for
25 you?

1 MR. ALDER: A vendor did this for us,
2 that's correct.

3 DR. MCNEIL: It would probably be very
4 useful to have that information; as a matter of
5 fact, it might be essential.

6 MR. ALDER: Yeah. Just some added
7 information. This compares very favorably with
8 some other procedures that are performed.

9 DR. MCNEIL: I actually understand
10 that. I guess what I'm -- I was very impressed
11 actually by the similarity of these mortality
12 rates, however the procedure is done, with CABGs
13 and hips and whatever. But I'm a little concerned
14 that I don't fully understand the mortality rates
15 and the complication rates for the over 65, and I
16 understand that getting complications from the
17 MedPAR file is probably impossible because we
18 don't know what preceded the patients admission
19 versus what occurred at the time of the admission,
20 so I'm willing to write that off as an
21 impossibility. But getting mortality data would
22 really be pretty important.

23 MR. ALDER: And I would agree.

24 DR. DAVIS: Greg.

25 DR. RAAB: A few moments ago, Dr.

1 Sugerman, I think you referenced a differential
2 access of Medicare beneficiaries according to
3 where they lived, the different types of
4 procedures. Is that due to the local coverage
5 policies, is that it? And I'm curious, maybe
6 Steve knows, what's the range of access? Is it
7 that a certain procedure is prohibited or
8 permitted in certain areas and not others, is that
9 it? I'd be curious, we're talking about the
10 Medicare population having access to bariatric
11 surgery, and I'm curious how much access there is
12 under the current system, what local review
13 policies are.

14 DR. PHURROUGH: I don't know what all
15 the 51 policies are for 51 different contractors,
16 but in general, my impression is none of them
17 non-cover, they don't have that option. Their
18 options are we have coverage, we don't define
19 except for diabetes and cardiovascular disease, I
20 believe. We don't define comorbidities other than
21 those two.

22 DR. RAAB: Are they restricting it to
23 banding versus bypass, or are they that specific?

24 DR. PHURROUGH: They do have the option
25 for defining some of the other procedures other

1 than bypass where we have a specific decision that
2 bypass is covered using the same comorbidity
3 issues. The other procedures, contractors do have
4 discretion to determine we're not going to pay for
5 that, and I don't know what the range of that is.

6 DR. DAVIS: Just to follow up on this
7 line of questioning, Dr. Barry Fisher mentioned
8 that some of the cases that he was involved in
9 were denied for coverage by the local carrier even
10 when comorbidity was present. I wonder if you
11 could explain what the situation was there.

12 DR. FISHER: Over the course of time,
13 as I said, we decided not to take on the Medicare
14 patient population. We were told to code the
15 patients with a 250.00, which is diabetes if they
16 had diabetes, as their primary diagnosis and we
17 would get paid. We were denied. We were told to
18 code them as 278.01, which is morbid obesity, and
19 put the 250.00, and every single case was denied
20 and had to be appealed. And frankly, for the
21 amount of time involved and the amount of
22 compensation, it isn't worth it. So we made a
23 business decision not to do Medicare patients
24 under the Medicare program until that situation
25 changes. That's why I argued for removing the

1 capability of a medical director for making a
2 decision based on medical necessity. The criteria
3 should be clear, should be unencumbered by any
4 conditionality, and that way if you want the
5 people to be covered, you want them to get the
6 surgery, that way you remove any judgment
7 decision.

8 DR. FLUM: David Flum. If I could just
9 echo one point there, it gets down to the issue of
10 they'll cover the procedure but it's the type of
11 procedure that they will allow. In Noridian,
12 which is the northwest regional coverage for 11
13 states, does not cover for the adjustable gastric
14 band. So you're asking where the data is for
15 patients over 65, and we simply can't provide it
16 to you because we can't do the procedure.

17 DR. RAAB: In those situations where
18 carriers have, they have medical directors for
19 each state but they're making all the decisions
20 for the entire geography, not state by state?

21 DR. FLUM: Well the Noridian medical
22 director, the director of the regional carriers
23 can make those calls. And just so you know, we're
24 waiting for this panel to help them make decisions
25 about coverage, because it really is a decision

1 that's made on that medical director level.

2 DR. RAAB: But doesn't that require
3 local carrier advisory committee input state by
4 state, geography by geography?

5 DR. FLUM: Yeah, but the message that
6 I've gotten is that they take the regional
7 carrier's lead. So for example, if the medical
8 director of Noridian said that adjustable gastric
9 bands seems like something we should cover, then
10 the states would follow.

11 DR. DAVIS: Is this an answer on this
12 same question.

13 MR. GARVER: Yes.

14 DR. DAVIS: Please.

15 MR. GARVER: Jim Garver, INAMED Health.
16 To answer your question specifically, because we
17 have looked at this on a carrier-by-carrier basis,
18 Noridian, Blue Cross of Kansas, and I just drew a
19 blank on the carrier for Florida, it is
20 principally a Part B issue where the physician
21 services are not being covered where many of the
22 Part A's are covering the hospital stay. So there
23 is a discrepancy, particularly when you have two
24 different intermediaries in a given state coming
25 up with separate policies.

1 DR. RAAB: Steve, would that go away
2 under the MMA provisions where the carriers have
3 to coordinate? No?

4 DR. PHURROUGH: We're probably getting
5 a bit far out of the evidence issue, but there are
6 MMA provisions that say we're going to have a new
7 contracting system in which the contractor for a
8 region will have the same Part A Part B, they will
9 not be separate Part A Part B contractors for the
10 same region anymore, but that's some time in the
11 future.

12 DR. RAAB: But for a given geography, I
13 thought it had a provision where fiscal
14 intermediaries and carriers have to coordinate.

15 DR. PHURROUGH: That is for new
16 policies, it's not retroactive to old policies.

17 DR. RAAB: Thank you.

18 DR. DAVIS: Dr. Buchwald was next on my
19 list.

20 DR. BUCHWALD: Thank you. I would like
21 to make a few remarks. I have been trying to
22 figure out what my role is as a guest panelist. I
23 have a vote, but my vote doesn't count, so I guess
24 that defines my role, and maybe it affords me the
25 privilege of making a few comments.

1 First of all, I wasn't sure when we
2 were saying our conflicts of interest if our
3 affiliations should be mentioned and I left a few
4 things out, such as I chair the Obesity Coalition,
5 which is a group of essentially every major group
6 in this country, like American Heart, American
7 Medical Association, American Dietetic, over ten
8 groups in this country that are all interested in
9 the treatment of obesity, and on this Obesity
10 Coalition I represent the American College of
11 Surgeons, and I have represented the American
12 College of Surgeons in an annual course on
13 bariatric surgery, putting out a CD-ROM, and as
14 the chair of the National Bariatric Surgery
15 faculty, so I wanted to put that into the record.

16 Now, a few remarks, if I may. Really,
17 what should a guest panelist do in terms of
18 helping fellow panelists? We should listen to
19 what we have heard, we should take a lifelong
20 experience, and the three guest panelists up here
21 have had a lifelong experience in this field, and
22 try to make it into some sort of a focus on where
23 we would think the situation should go, and I made
24 a few points for myself.

25 Number one is, we've heard that we need

1 more data, and there is no physician, there is no
2 scientist in this world that would deny that we
3 need more data probably in every field, and
4 certainly in this field. And having made that
5 statement, the question is where do we go from
6 there. It would be wrong to say we don't have the
7 data, therefore, we cannot make any decisions, or
8 we should deny coverage so that we will never get
9 the data. On the contrary, we should say we
10 should focus on demonstrations, on maybe a
11 Medicare demonstration program that will bring out
12 the data that is currently missing.

13 So the fact that we have no data on
14 many of these aspects, people over 65 and so on,
15 is not a negative comment, it's a progressive
16 comment looking to the future, and we must obtain
17 these data, and to obtain these data we have to
18 extend coverage and record what happens to these
19 groups that we don't know that much about.

20 Another point that has been made before
21 but it probably should be reemphasized, that there
22 are probably no patients, especially over the age
23 of 65 who do not have comorbidities, so I know why
24 the question has to be asked, but it's being asked
25 about a population that generally does not exist.

1 Because if you talk to any person who is morbidly
2 obese, they will have a comorbidity.

3 The other thing I want to make a
4 comment on is, it is the standard of care in our
5 society to treat disease and to treat it as soon
6 as possible. We don't wait for colonic polyps to
7 become colonic cancers. We don't wait for little
8 breast masses to become big breast masses. We
9 treat a chemical abnormality of the blood,
10 hypercholesterolemia, to prevent the inevitable
11 death that will ensue if it is not treated. We
12 treat the physiologic abnormality of high blood
13 pressure to treat the inevitable death if it is
14 not treated. And therefore, asking the question
15 of patients, even if they existed, who have
16 minimal or no comorbidities, should one treat
17 them, goes against the entire spectrum of our
18 standard of care. We know that the morbid obesity
19 is going to kill them so why shouldn't we treat it
20 as soon as possible, rather than say let's wait
21 until they get a comorbidity, let's wait until
22 this happens.

23 I'm honored that our meta-analysis
24 paper has been mentioned so many times. What does
25 that show in one sense in terms of the

1 comorbidities? If you take a patient who comes to
2 you as a physician who has diabetes, type 2
3 diabetes, hypertension, hyperlipidemia and
4 obstructive sleep apnea, and you treat all of
5 these conditions, you're going to end up giving
6 that patient a whole lot of pills, putting him on
7 an instrument to sleep at night, and you're not
8 going to treat any of those diseases really.
9 You're going to mitigate them, you're going to
10 make the patient feel better for a period of time,
11 but the diseases continue insidiously to work
12 towards a fatal conclusion.

13 If you treat the morbid obesity, which
14 is the primary disease that causes all these other
15 diseases, you're going to get rid of not only the
16 morbid obesity but you're going to get rid of
17 these fatal diseases.

18 I listened to a comment talking about
19 prevention and how important it is to prevent.
20 Nobody in the world would deny that it is
21 essential to prevent morbid obesity if we possibly
22 can, but that begs the question, what are we going
23 to do with the people who are morbidly obese?
24 Nobody today would say we shouldn't treat AIDS,
25 we should only concentrate on preventing it. We

1 shouldn't treat diabetes, hypertension, we should
2 only concentrate on preventing it. We have to
3 treat the people who have the disease in addition
4 to preventing.

5 The question of which is the best
6 operation. There is no answer to that question,
7 because it is a non-question. Which is the best
8 operation for what? Which is the best operation
9 in terms of engendering weight loss? Well, you've
10 seen those things, they're up there. Which is the
11 best operation for risk? Those data have been
12 presented and it's a different answer. Which is
13 the best operation for comorbidities? Probably
14 all of them. And then which is the best operation
15 for patient satisfaction, which we haven't really
16 even talked about today, quality of life, patient
17 satisfaction. So how does one make this decision?
18 I think this is a decision that's best left to the
19 patient and to the surgeon and it should not be
20 left to a panel, it should not be left to any sort
21 of set of instructions. Nowhere when any
22 insurance body, Medicare governs fixing a hernia,
23 do they say we want you only to do a Kugel repair,
24 or we want you only to do a Lichtenstein repair.
25 I think this belongs in another spectrum of

1 discussion.

2 And I guess that's more or less what I
3 have to say. I think we're only here for a
4 certain reason today, that the morbidly obese are
5 a segment of our population that is still
6 subjected to a great deal of bias and prejudice,
7 and therefore the treatment of the morbidly obese
8 is subjected to a certain amount of bias and
9 prejudice. If we were talking about other
10 diseases, there wouldn't be this conflict, or
11 should we extend to it to people with early
12 disease and so on. I think we have to get beyond
13 the bias. Obesity is the last permitted prejudice
14 in our society, and we must not permit it anymore.
15 We have to say that obesity and morbid obesity in
16 particular is a disease and that today the
17 treatment of choice is bariatric surgery. And I'm
18 sorry I was long winded.

19 DR. DAVIS: I appreciate your comments.

20 (Applause.)

21 DR. DAVIS: Dr. Buchwald, I just want
22 to interject here that I don't think it's only a
23 matter of maybe a double standard between obesity
24 and other issues. There is a double standard
25 between treatment and prevention, and we struggle

1 with getting Medicare to pay for a lot of
2 preventive services. Medicare doesn't pay for
3 smoking cessation treatment today although it is
4 now looking at that issue, although of course it
5 pays for treatment of lung cancer and heart
6 disease and stroke, and everything else caused by
7 cigarette smoking. So you have to figure out a
8 way to allow Medicare to pay for something that's
9 preventive by figuring out how to consider it to
10 be a treatment. Well, it's a treatment of tobacco
11 dependence, which is then ICD-9 and DSM-IV. And
12 similarly, it's the comorbid condition that allows
13 CMS to pay for this under existing law. So, I
14 think that certainly there are issues relating to
15 obesity, but there are also vagaries of the law
16 that authorizes Medicare that I think also come
17 into play.

18 DR. BUCHWALD: And fortunately the law
19 has been amended, so that obesity is a disease, or
20 at least in terms of the strict law, obesity can
21 no longer not be considered a disease.

22 DR. DAVIS: That's it, yeah, the rule
23 was changed so it doesn't say that it's not a
24 disease.

25 DR. BUCHWALD: They spoke in a double

1 negative, but if I can eliminate the double
2 negative, obesity is a disease.

3 DR. DAVIS: I think Dr. Sugerman was
4 next. No, Dr. McNeil.

5 DR. MCNEIL: I would like to go back to
6 one of the earlier questions. I must say that on
7 average as I look at all of the data, it's very
8 impressive, and I am quite taken by the results.
9 But I am really still disturbed by one thing, and
10 it's the following: It goes back to Jed's
11 question. I had the feeling from listening to
12 some of the individuals in the audience that many
13 of the speakers did a particular procedure and
14 that was their procedure, though they might do
15 others, but they really really liked whichever one
16 it was.

17 So then I was trying to decide if a
18 patient came to, even if it's a center of
19 excellence in a hospital with, say, 3 or 400 beds,
20 what is the chance that a patient would have
21 access to a surgeon who did all, say six, open and
22 laparoscopic procedures at a number greater than
23 50 a year, and how would the internist know which
24 physician to send that patient to?

25 That's the thing I'm totally confused

1 about, because I understand the data in the
2 aggregate, I'm totally convinced, I understand the
3 reduction in comorbidities post-treatment, I have
4 all that, so I don't want to talk about that
5 aspect of it at all. I'm much more interested in
6 understanding from a real quantitative view point,
7 what are the risk selection criteria that are
8 involved in sending a patient to procedure one
9 versus procedure two, and I can't find it in any
10 of these articles and it's got to be there, with
11 all of this writing, someone's got to have done
12 that. So I don't want a qualitative answer, just
13 to be clear.

14 DR. BLACKSTONE: Let me first say that
15 when you're beginning to develop a program in
16 bariatric surgery, which we've had experience
17 with, you I think need to start with a procedure
18 around which you can build a comprehensive
19 approach where your understanding of the data, if
20 you're going to do evidence-based and data-driven
21 medicine to the extent that that's possible allows
22 you. And so in our view at the time that we
23 started our program in 2001, that pretty much
24 meant gastric bypass Roux-en-Y, we had the most
25 data, we had the best system of care, and we knew

1 what the benchmarks would be for outcomes from
2 what had been published.

3 Patients seeking surgery do extensive
4 research on the Internet, to your point. Most
5 patients will come in with a year or more of
6 research, they have been to many different
7 presentations by different centers, they spend a
8 lot of time and energy themselves selecting and
9 trying to discern from the information that they
10 have what the best procedure they think is for
11 themselves.

12 When laparoscopic banding became
13 available through the FDA, we actually waited
14 about six months to adapt it, because we had to
15 adapt our entire system to it. It's a little
16 different training, a little different education
17 about nutrition because you don't interrupt the GI
18 tract, and these issues have significant clinical
19 implications for how you care for patients.

20 So when a patient comes now and they
21 say Dr. Blackstone, I have been reading about this
22 for a year and I really want a lap band or a
23 gastric bypass, we then look at the food journal
24 they've submitted, we get the data from the
25 nutritional consult they've just had, we look at

1 their psychological profile, and together with the
2 patient we make a decision, and to my knowledge
3 that is not actually quantified anywhere, that
4 process.

5 We do not do the duodenal switch right
6 now, it's a malabsorptive procedure primarily and
7 because of that it requires, again, an entirely
8 different strategy among your supporting allied
9 health team. And in your clinical pathway of
10 care, it's a whole different clinical pathway, and
11 so to adapt that, which we may do, we really need
12 to be convinced that we have a population of
13 patients to whom it will be most applicable, and
14 in my judgment the evidence was that it was less
15 applicable in my population. I could get very
16 good resolution of comorbidities with the bypass
17 and the band, and so we haven't offered it.
18 However, if we were to see a patient who we
19 thought would be best served by it based on what
20 we know, we would refer them to a surgeon who does
21 a significant number of switches or BPDs, so that
22 they could be evaluated for that procedure there.

23 DR. MCNEIL: Could I just ask a
24 follow-up question, Ron? Could you just give me a
25 little scenario of how that patient that you just

1 referred somewhere else, what would be the
2 characteristics of that patient that would be
3 different from the patient that you kept in house?

4 DR. BLACKSTONE: Primarily it would be
5 someone who, A, had a strong bias themselves to
6 the procedure. Again, you know, as you know, in
7 real life when you're working with a patient and
8 they come in with a year and a half of duodenal
9 research data and say this is what I want, then
10 even if you think they may be able to achieve
11 those results with bypass, I think you owe it to
12 them to allow them to be evaluated by someone who
13 is very good and has a system that supports the
14 switch.

15 DR. MCNEIL: Would you be saying, then,
16 I just want to be absolutely clear I get this
17 because I still don't have it, would you be
18 saying, then, that in the vast majority of cases,
19 the patient should be the decision maker as to the
20 type of surgery, and the results will be
21 essentially the same in terms of short and
22 long-term mortality, major complications, and
23 approximate weight loss?

24 DR. BLACKSTONE: I think that their
25 preference for the type of procedure has a role to

1 play. I think that we see patients that we don't
2 think are appropriate for one or the other, and
3 then we work with them and talk with them about
4 why we think that is.

5 DR. MCNEIL: Could you just give me an
6 example of that, because I really still, I'm not a
7 surgeon and I don't see how this works.

8 DR. BLACKSTONE: I can tell you in my
9 particular bias right now, based on our results
10 and what I've observed, if we have a patient who
11 is diabetic, we will often suggest to them that we
12 think that the bypass gives better long-term
13 results for diabetes right now, based on what we
14 know. And that might be a more concrete example.
15 Some patients' behavior patterns may not be as
16 good for the band. Again, you're weighing that
17 against their profile. And this is one of the
18 things that I wanted to mention about our
19 population. Obviously if you have a procedure
20 that is less risky that you can offer to an older
21 group of patients who you wouldn't maybe think
22 were good patients for the bypass, for instance,
23 then there is a way to differentiate. You know,
24 you want to be able to offer some less risky
25 procedure to those patients if they can get a

1 reasonable amount of resolution of their
2 comorbidities and improved quality of life for
3 less risk. So you know, I don't know if I'm being
4 -- you know, it's not as straightforward perhaps
5 as that.

6 DR. MCNEIL: Well, just if I could push
7 this just one little second more.

8 DR. BLACKSTONE: I'm not sure I'm glad
9 I got up here.

10 DR. MCNEIL: It sounds as if you run a
11 fabulous service and are extremely generous and
12 altruistic in sending patients out, so that if a
13 patient came in and your particular service didn't
14 offer the switch procedure, for example, you would
15 send them out. Do you think that happens
16 everywhere, and if it doesn't, then is it possible
17 that a patient is really going to get a suboptimal
18 procedure? And now I'll stop.

19 DR. BLACKSTONE: It would be arguable
20 among my colleagues whether a bypass could ever be
21 considered suboptimal to a switch. The
22 differences in who would be good for one or the
23 other might be a little bit, you know, that might
24 be hard, so I'm not sure if you couldn't send
25 someone out would be. But the truth is, there are

1 very good people doing switches in the U.S. that
2 we could send the patient out to, and we would
3 argue and lobby for that if it we felt that was
4 the right procedure for them. You know, I think
5 that it's important when you're a responsible
6 surgeon to grow up to the point that you realize
7 that perhaps you're not the person who should do a
8 Whipple if there's someone down the street who
9 does 50 of them a year who might be really really
10 good at them. And I think that it's important
11 when you're thinking about patient outcomes and
12 quality to always go there so that that's your
13 primary driver.

14 DR. BUCHWALD: Could I take a crack at
15 that?

16 DR. MCNEIL: Well, I wish you would
17 because I'm still very confused.

18 DR. BUCHWALD: You still look
19 skeptical.

20 DR. MCNEIL: Well, I'm not skeptical,
21 but I guess I don't have enough trust, to be
22 perfectly honest, in the system as a whole to know
23 that a physician, that a primary care -- not
24 enough knowledge, trust and knowledge about this
25 as a whole, to know that an internist would know

1 what kind of bariatric surgeon to send a patient
2 to and to be sure that that bariatric surgeon
3 would say no, I'm not the right one for you, you
4 need another procedure, please go across town to
5 the Mass General and leave the Brigham, just for
6 instance.

7 DR. BUCHWALD: I don't know if I can
8 remove your mistrust, but let me try a few things.
9 First of all, in my own community, Minnesota, in
10 my own center, we do them all, so that answers one
11 question. We do the whole range. We have
12 seminars with the patients and we let the patients
13 decide, and that maybe answers another question,
14 who should be the ultimate decision maker, the
15 patient. We might guide them but the ultimate
16 decision maker should be the patient, just as the
17 patient is the ultimate decision maker on what to
18 do for prostate cancer, what to do for atrial
19 fibrillation, should they be put on Coumadin or
20 should they try to be defibrillated and their rate
21 controlled. These are decisions that the
22 physician has to make together with the patient.
23 All right.

24 The second thing is, so what happens in
25 our own community when somebody comes in to

1 another surgeon or to another group of surgeons
2 who do not do the duodenal switch? They send them
3 to us. And then to give you a little trust in the
4 system, there are today at least two million
5 people that would qualify under the NIH standards
6 for bariatric surgery. We're doing about 140,000
7 cases annually, so we are serving 1 to 2 percent
8 of the population. Where would this be accepted
9 if we would be saying we're only going to serve 1
10 to 2 percent of the diabetic population or the
11 hypertensive population, but we're really only
12 serving 1 or 2 percent. So if there is anything
13 but an altruistic feeling like the patient is
14 mine, the patient is mine, I don't think it
15 exists. All of us who are in the field have
16 waiting lists for a year, or two years, and
17 therefore, if a patient wants a particular
18 operation and it's not something that's being done
19 in that center, it's no hardship to say you go
20 over there, because they do it well.

21 DR. DAVIS: Dr. Klein.

22 DR. KLEIN: This is changing track
23 completely. I wanted to get to the issue of
24 comorbidities and what that means in the elderly
25 population, because the term has been bandied

1 around but I'm not clear we understand what
2 exactly is being meant by the term comorbidities
3 and how that will be defined in the population
4 over the age of 65. Because in that group, BMIs
5 even of 30 to 35 range can potentially impair
6 quality of life and be a comorbid condition. In
7 fact in our own experience, a BMI of 35 to 40
8 results in practically 100 percent of elderly
9 people being frail according to the standard
10 criteria of frailty in older people.

11 So if we could get to some kind of
12 decision about what comorbidity means in the older
13 population, it may be different in the younger
14 population, and if that's the case, then there is
15 no reason to have this meeting, because all we're
16 doing is talking about considering this procedure
17 in people who don't have comorbid conditions.

18 DR. COWAN: George Cowan. I have
19 talked and I have not had anybody state otherwise,
20 that there are five main classes of comorbidities.
21 One is medical, and that's what most people focus
22 on, the diabetes, the sleep apnea, the swollen
23 ankles, the shortness of breath with exertion. It
24 goes on over a hundred items.

25 The second one is social. Yes, social,

1 the prejudice that people have alluded to and such
2 like, which can be an extremely strong comorbidity
3 in and of itself that people live under. They are
4 down to their last two friends. Dr. Wadden
5 covered that.

6 Thirdly is psychological or psychiatric
7 and again, that has been addressed.

8 Fourth is physical. Where do you find
9 a size 60 panties? How do you get a 500-pound
10 person into a small Volkswagen? Those are the
11 various things where people just don't fit into
12 the movie theaters, the planes, the trains,
13 et cetera.

14 And fifth is economic. Some people
15 argue, is this a comorbidity? Well, if you can't
16 get a job, I maintain it is, just because you're
17 fat, but you're better than anybody else at doing
18 what you do. And when you don't have the bread,
19 you don't keep the family together, you have
20 psychosocial dynamics that are extremely
21 dysfunctional, and again, it becomes a significant
22 comorbidity.

23 So when you talk about comorbidities,
24 yes, for big people you can find a comorbidity for
25 everybody if you want to go along those five major

1 groups. What you maybe saying is, what is a
2 significant comorbidity and how do you define that
3 particular comorbidity? But it's out there. When
4 you weigh a hundred pounds or more overweight, you
5 are subject to all of the nastiness that the
6 American population can provide, and I'm sure you
7 will agree, there is a lot of it out there in
8 addition to the medical, social, psychological,
9 and physical comorbidities.

10 DR. KLEIN: I'd like to know, what does
11 Medicare consider a comorbidity for this
12 procedure? I couldn't find it in the documents.
13 I may have missed it.

14 DR. PHURROUGH: We don't define it, we
15 give two examples, and I don't suspect we will
16 ever define it. We may give more examples based
17 on some of the information here, but it would be
18 very unlike Medicare to try and define it. One
19 reason we took out the comment, obesity is not an
20 illness, is that we in general are not in the
21 habit of telling the medical world what is and
22 isn't a disease.

23 DR. KLEIN: Would it be under the
24 purview of this panel to say for the elderly
25 population, a reasonable comorbidity is poor

1 functioning, poor physical function of life, and
2 that's it?

3 DR. PHURROUGH: The panel has a lot of
4 freedom to do what it wants to outside of
5 answering the questions, but if you would like to
6 advise us what you think comorbidities are, then
7 we'll take that into account as we look at your
8 recommendations.

9 DR. DAVIS: Do the NIH guidelines
10 define comorbidity.

11 DR. KLEIN: Very vaguely, and physical
12 function is one of the comorbidities that they
13 define, but not one that's accepted by any
14 insurer.

15 DR. SUGERMAN: They don't define it for
16 a BMI of 40 or greater, but there are no examples
17 of comorbidities, but I think that's the issue,
18 that there are so many of them. I mean, there are
19 so many of these comorbidities, BMI of 40 or
20 greater, and then they do define it for the 35 to
21 39 in terms of sleep apnea, degenerative joint
22 disease, obesity, hyperventilation, and so forth.

23 DR. DAVIS: Does anybody want to
24 continue on this point? I have a list of people
25 who want to get off into other areas, I presume,

1 but if people want to speak to this issue, we can
2 take them out of order.

3 DR. PHURROUGH: Let me make one more
4 comment about comorbidities. Anytime we define
5 something with a list, then there's always a
6 problem, because something is left off the list or
7 something that's on the list suddenly shouldn't be
8 on the list. Obesity isn't a disease. Well, it
9 shouldn't be on the list of what isn't a disease,
10 and it takes an act of CMS to change that. So
11 creating lists are always problematic, so our
12 preference is not to do that, though we have
13 chosen in some cases to do that.

14 DR. DAVIS: Dr. O'Connell.

15 DR. O'CONNELL: Well, my observation
16 here is that we started off with NIH guidelines of
17 35 plus comorbidities and 40 and no comorbidities.
18 And we've learned from at least one of the
19 speakers earlier today that even below 35 there
20 may be comorbidities that would make some kind of
21 intervention necessary. And to me this is like a
22 fuzzy moving cloud; when is in fact bariatric
23 surgery necessary, and we as a panel are sitting
24 here and the thoughts are going through our minds,
25 but I see a big void in the bariatric community

1 not coming forward and being actually proactive
2 and saying wait a minute, you should do it here,
3 whether that be 32, 38 or 48, but I don't see
4 that. What I see is you arguing back and forth
5 whether you should do a lap band, or a duodenal
6 switch, or representing one company or another,
7 and it makes it very difficult for panel members
8 to try and decide something like this.

9 DR. DAVIS: Dr. Margolis, did you want
10 to chime in on this issue?

11 DR. MARGOLIS: I guess my question is
12 somewhat along that line, although from a
13 different point of view. I can either wait or ask
14 it now.

15 DR. DAVIS: Is it on the issue of how
16 to define comorbidity?

17 DR. MARGOLIS: No, no, not comorbidity,
18 who the procedure should be done on.

19 DR. DAVIS: Then if you could hold off.

20 DR. MARGOLIS: Which is what I think
21 he's addressing. He's not really addressing
22 comorbidity anymore, he's addressing who should
23 get it.

24 DR. DAVIS: I want to be fair to Steve
25 Phurrough, who got on my list, and Mike as well.

1 DR. PHURROUGH: That was earlier and I
2 don't remember what my question was.

3 DR. DAVIS: Mike, do you remember what
4 your question was?

5 DR. ABECAASSIS: Well, I wanted to
6 follow up on Dr. McNeil's comments, because I'm a
7 surgeon and when I was training I did more
8 vertical banded gastroplasties than I care to
9 remember. And you know, that was the panacea at
10 the time, and now there are other procedures, and
11 we're hearing about the benefits and the merits of
12 each procedure. And I just read a paper that came
13 out last month where, I think it came out of
14 Minnesota, but it was actually the other
15 institution in Minnesota, that said that they had
16 a large series of patients that they were now
17 doing a second procedure on where they had failed
18 years after the first procedure, and the first
19 procedure in this series was the VBG and now they
20 were doing Roux-en-Y. So I'm kind of wondering
21 along the same lines. Are there patients that the
22 surgeons in the audience think are going to get a
23 banding procedure, for example now, and then if
24 they plateau or regain weight on that, are then
25 going to be candidates for either a Roux-en-Y

1 procedure or duodenal switch procedure? Are these
2 procedures mutually exclusive or is this a
3 spectrum of procedures, because I'm also confused
4 as to who would get what procedure right now.

5 DR. KRAL: John Kral again. I would
6 like to take this opportunity to address really
7 rather related questions. Patient selection is
8 really what you're talking about, Dr. McNeil, and
9 you alluded to that again. And you,
10 Dr. O'Connell, asked for criteria, do we have a
11 moving target here or what's going on.

12 It all begins with the extraordinary
13 biases out of which this whole field sprang, and
14 our current understanding of obesity is rather
15 different than it used to be. It's not many years
16 ago we learned that it has to be treated like a
17 chronic disease. It is no longer suggested that
18 one provide treatment for 10 weeks, 15 weeks, and
19 that is the end of it. Nobody would ever have
20 suggested that about hypertension or diabetes, but
21 that's actually what was suggested just until a
22 few years ago. So it is a moving target and the
23 standard has evolved and it has evolved from a
24 rather, I would say hazardous type of surgery
25 before we had learned how to operate on very heavy

1 people. So that's why the border has been
2 shifting, it has been moving downwards.

3 I predict that we're going to see those
4 hard and fast body mass index levels, and I can
5 tell you that I was the initiator of the consensus
6 conference in '91 and one of the people who led
7 putting together that program at that time. It
8 was a panel, an independent panel that reached the
9 conclusions. And that was based on the
10 practicality of what was feasible and possible to
11 get any kind of acceptance for.

12 Since then we've had the advent of
13 laparoscopic approaches, which is a real change in
14 our ability to provide safer care, at the same
15 time as the field has been evolving. And with
16 that has our understanding of, number one, our
17 ability to provide a more effective treatment at
18 lower levels of body mass index.

19 And abstracts have been presented on
20 the study done in Australia using a laparoscopic
21 banded approach in a prospective randomized, and
22 I'm the enemy of randomized trials, but here it
23 was done for ethical reasons in patients with a
24 body mass index 30 to 35, because it was
25 considered unethical to randomize above that level

1 because you didn't have an alternative equipoising
2 in the nonsurgical arm. And it of course wasn't
3 ethical to go below 30 where you couldn't be
4 certain that the disease mandated that level of
5 intervention.

6 And that's a significant change and
7 it's not addressing the issue, but it's just
8 explaining why you're not getting hard and fast
9 criteria because no one has even dared to
10 enunciate them. So it's very nice to have this
11 study of 30 to 35 body mass index where it
12 actually provided carefully and safely, and doing
13 a better job than anything else has been able to
14 do.

15 Back to the crucial issue, who are you
16 going to refer to whom, why and how, and what
17 criteria can you use? Dr. Buchwald and I are
18 probably those who go furthest back in time in
19 performing surgery for obesity, the early '70s. I
20 have, as Dr. Buchwald implied that they had done
21 in their center, have performed and provided all
22 of the modalities available up until the
23 laparoscopic approaches became available, and I
24 have not learned and not provided myself complex
25 laparoscopic procedures because I was not willing

1 at my stage in life to overcome that level of the
2 learning curve.

3 In providing all of those modalities,
4 let me first say, there is not one shred of
5 evidence that there are selection criteria for
6 predicting, and I've wanted to do this my whole
7 career, I've spent my whole life trying to figure
8 out what is an optimal method of treatment, of
9 surgical treatment among the various wrinkles and
10 facets of technical variance of surgery. There is
11 no hard data on this.

12 However, let me address with you, Dr.
13 Abecaassis, since you just brought it up, already
14 at the NIH consensus conference, I proposed and
15 had proposed earlier that one probably needs to
16 take the same approach to this disease of severe
17 obesity as one does in some other diseases, and
18 that's to have a staged approach, and that staged
19 approach includes surgical modalities. Where I
20 think it is fair to say that a laparoscopically
21 placed band might, if nothing else, succeed in
22 selecting patients who with failure of that
23 procedure would be eligible and reasonable to
24 provide a more aggressive, possibly more
25 dangerous, but over the long term more effective

1 procedure. So a staged approach is not
2 unreasonable. It's not a failure of the whole
3 field that people are seriously considering that
4 revisional surgery might be necessary. Because we
5 do not have those criteria doesn't mean it's all
6 bad. But we do not have hard data and I have a
7 perspective, a little more than the one you heard
8 about from before from 2001.

9 DR. WOLFE: Bruce Wolfe. I would just
10 like to offer a couple of quick comments that
11 might perhaps help understanding of a couple of
12 the issues.

13 Number one, the potential confusion
14 over the issue of the patients who do or do not
15 have comorbidities is presumably impacted by the
16 fact that a given population of patients with a
17 BMI of 45 and a certain age who seek surgery has
18 declared in their own mind that the risk of the
19 surgery is worth it if they don't have the
20 metabolic comorbidities, but they have self
21 selected their psychosocial impact, whereas a
22 patient who doesn't seek surgery has a lesser
23 psychological or psychosocial impact. That isn't
24 really studied because at surgical centers we
25 don't see that whole population of people who

1 doesn't come seeking the treatment.

2 I mean, personally, if the patient
3 doesn't have diabetes or the more common
4 comorbidities, I say to the patient well, what is
5 it about being overweight that leads you to seek a
6 life threatening treatment? I mean, there's got
7 to be something bad about being 300 pounds that
8 you would be willing to take on this risk. And if
9 they don't understand the risk, then you've got to
10 start over and make sure that they do.

11 And if you go through that process then
12 there probably is some self selection of who these
13 patients are, and if you go that route, then you
14 can say yes, they all have comorbidities because
15 we don't operate on people that don't have
16 comorbidity.

17 Now, this question of how do you decide
18 which operation is best for which patient is a
19 very good question. Dr. Buchwald and Dr. Pories
20 have both already alluded to the fact that we
21 don't actually have clear data with criteria on
22 how to make such a selection. You go back just a
23 step and say well, what are the mechanisms by
24 which these operations actually work? I mean,
25 coming up with a treatment, it's nice to know the

1 details of the pathophysiology and what the
2 mechanism of action is of the intervention that
3 one proposes.

4 As it turns out, we don't actually know
5 how these operations work in detail, we don't
6 really know exactly why are there successes and
7 there are failures. For example, there are so far
8 ten gut peptides that have been identified, from
9 Agrelin in the stomach to PPY-3 in the colon, that
10 are regulators of appetite and satiety and when
11 they go up to the brain and affect the CNS
12 centers. How those interactions related to the
13 receptors in the brain and affect appetite is not
14 known, but certainly is involved in the
15 determination of how a given operation works.

16 The idea that the stomach is made small
17 and that that's how they lose weight or the idea
18 that they malabsorb is hopefully oversimplified
19 and in fact not correct, and it is beyond the
20 scope of today's meeting to get onto those issues.
21 But until those matters are better defined, it's
22 going to be difficult for us to come up with
23 better predictors of exactly which procedure will
24 be best for which patient. Now we're going with
25 some pretty crude associations, for example, a

1 more severely obese patient is less likely to
2 achieve a satisfactory or healthy BMI as we call
3 it, but that, there is no data at this time that
4 says one procedure or another should be done
5 because of that circumstance.

6 If we knew that they had some different
7 secretion of Agrelin and PYY, then perhaps there
8 would be a basis. So it's premature for us to
9 really be able to develop clear guidelines on
10 which procedure is best. Hopefully, more research
11 will help us to identify those factors.

12 DR. DAVIS: Thank you.

13 DR. SUGERMAN: If I could just add one
14 last comment, I think the best procedure is the
15 one that the surgeon really knows how to do well
16 and safely, and the worst would be that there be
17 some demand that every surgeon perform every
18 procedure. I think the clear-cut issue is that
19 the surgeon does a quality operation with quality
20 care of the patient, and any of the procedures
21 seem to be effective in the right hands.

22 DR. DAVIS: Dr. Fisher.

23 DR. FISHER: I will try to be brief. I
24 think what you should take away from this is that
25 there is no one operation that is better or

1 perhaps no one operation that is better for a
2 specific identifiable group of patient subgroup,
3 because I don't think any of the data that has
4 come forth has demonstrated that. So you
5 shouldn't concern yourselves with that, you should
6 concern yourselves with whether patients should be
7 covered or not.

8 And just as you don't concern
9 yourselves with whether an internist prescribes a
10 calcium channel blocker or a beta blocker as the
11 first line of defense against hypertension, that
12 you leave to the doctor. And here again, I think
13 you have to leave to the surgeon the choice of
14 surgery that works well in their hands, just as
15 internists use specific medications.

16 Don't look back. We no longer use
17 Rauwolfia alkaloids because things have changed
18 and gotten better. So don't look back and compare
19 to years ago. Today we have laparoscopic surgery
20 that is being provided and all of the operations
21 can be performed in appropriate settings that way.

22 We designed, and the reason I have the
23 data that I presented to you today is that in 2001
24 when the band became available, I asked the
25 question and we're testing it, that if we use the

1 same preoperative training and same postoperative
2 program, is the program more important than which
3 operation is performed. And I don't have data
4 that goes out five years yet, but in another three
5 I will have valid data that I will be able to
6 present and answer that question. Right now I
7 don't have that question, but that's the
8 long-range study that we've been doing in our
9 community program.

10 So I ask you, don't concern yourselves
11 with things that we don't have answers to, like
12 the best procedure. We have accepted standards by
13 which we've been performing bariatric surgery
14 which have not been overtly challenged. The BMI
15 of 40 was accepted since 1991, it's been accepted
16 not only and recommended by the NIH, but also by
17 the American Obesity Association, and even appears
18 in the guidelines of InterQual and Mill &
19 Associates, and if it's widely accepted, that is a
20 good baseline place to start. If that population
21 becomes well served we will be doing a tremendous
22 boon to our society.

23 DR. PORIES: I think Dr. O'Connell
24 deserves a straight answer, and I think the
25 straight answer is there are some clearly defined,

1 it's not a moving target. The NIH guidelines of
2 35 plus comorbidities and 40, the age from 18 to
3 65, the business that if you have someone with
4 alcohol abuse or substance abuse or uncontrolled
5 depression is contraindications, those things are
6 excellent standard good guidelines that virtually
7 everyone follows. They are hard, they are fast.

8 Now obviously we're testing the edge of
9 the bubble because there are problems. We have
10 morbidly obese adolescents, we have people over 65
11 who are morbidly obese, and so on, and in many
12 cases those are being tested under IRBs under an
13 appropriate setting in a controlled setting.

14 One of the main reasons for setting up
15 the centers of excellence is to collect large
16 controlled databases, perhaps on a practical
17 basis, but at least that will allow us in a year
18 or two or three to see how effective these things
19 are. But I don't want you to walk away and say
20 there aren't any guidelines because there really
21 are.

22 DR. DAVIS: Let me go back to Dr.
23 Phurrough and then Dr. Margolis, and we'll pick up
24 where we were.

25 DR. PHURROUGH: I think Dr. Wolfe

1 finally answered the question that we've been
2 looking for, there are no criteria by which you
3 can define which procedure is a better procedure.

4 MS. ALBERS: May I as a patient say
5 something quickly about that?

6 DR. DAVIS: Sure.

7 MS. ALBERS: Every senior I know, and
8 I'm talking about in different socioeconomics,
9 we're pretty computer savvy today. We either own
10 computers, we go to libraries, we research. We
11 don't just walk into a doctor and say I'm fat, I
12 want surgery. I'm overweight, I want surgery.
13 And we don't, if a doctor says you need surgery,
14 just walk away and have surgery. We research, we
15 go on line. There are groups that you can go to
16 where you belong because you're thinking of it,
17 for all the types of surgery. We are entitled to
18 have a good input in the final decision because
19 we're the ones that are going to live with this.

20 DR. DAVIS: Thank you. Dr. Margolis.

21 DR. MARGOLIS: My question is a little
22 bit different although somewhat associated with
23 what's been going on. The data that's been
24 presented is very nice, and it has certainly been
25 well presented in both qualitative and

1 quantitative ways in the packets that we received,
2 and well reviewed over the last several years.

3 I guess my concern gets to some of the
4 points that have recently been made that there's
5 both a lot of patient self selection in terms of
6 having surgery, but the amount of people who could
7 have bariatric surgery is basically underserved,
8 and that the patients who have been studied so far
9 or have been reported on so far are really a very
10 small select group that have both had, it sounds
11 like very good pre-care and very good post-care as
12 has been described here, but it's a very small
13 percentage of everybody who could have surgery,
14 that they have to be very self motivated to find
15 the people and find the insurance companies to
16 actually pay for it. So I guess my question is
17 how do we know that what's been presented and
18 what's been so well summarized is really going to
19 be what we find in four or five years when more
20 and more people are having the surgery?

21 DR. DAVIS: Dr. Goodman, did you want
22 to answer that?

23 DR. GOODMAN: I wanted to support the
24 question before it's answered, I have a corollary
25 to that so as not to waste time. To the extent

1 that these procedures are regarded widely as safe
2 and effective and they are accorded more public
3 attention as they are today, demand is bound to
4 increase. And this demand is bound to stretch the
5 definition of comorbidities, it's bound to lower
6 the BMI, the threshold BMI. And with an aging
7 more obese population and the financial and
8 professional incentives which always prevail,
9 we're going to experience some kind of indication
10 creep, sometimes called the woodwork effect. And
11 so therefore, isn't it likely that some
12 significant new population distribution is going
13 to emerge as indicated for these procedures,
14 regardless of which one you happen to prefer, for
15 whom we know that we have precious few data, let
16 alone rigorously generated data. I'm talking not
17 much data, let alone the good stuff.

18 And so, this is potentially some shaky
19 ground. And this isn't confined to this type of
20 surgery, this condition, it's seen throughout
21 various procedures, interventions with which
22 Medicare has to deal. So therefore, we have to
23 give Medicare, as well as the patients and their
24 doctors an evidence base and clear criteria that
25 will enable them to respond to this anticipated

1 emerging patient population that's going to come
2 forth with these procedures. So I'm consistent, I
3 hope with Dr. Margolis, what's the basis upon
4 which we can be ready for this change in
5 distribution if it's going to be some people with
6 whom we're not quite familiar?

7 DR. DAVIS: With the whole flu vaccine
8 debacle, we've been dealing with this question of
9 prioritization and poor access to diminishing
10 supplies, so your question kind of rings loudly in
11 my ear, having dealt with the flu vaccine
12 situation over the last couple of weeks. Yes, Dr.
13 Sugerman.

14 DR. SUGERMAN: Well, I want to answer
15 that from at least our society's point of view
16 because we wholeheartedly agree with both of you
17 and with Mr. Phurrough that we really do need
18 data, much more data than selected series. We
19 need broad population-based data, and I think
20 we're going at it in a step-wise manner, starting
21 with the NIH-funded labs project where they are
22 now collecting and developing plans on how to rank
23 severity of illness so that the results can be
24 risk adjusted just like it is for coronary artery
25 bypass surgery. And then to the centers of

1 excellence in which as part of being a center of
2 excellence, you plus submit your outcomes data,
3 and furthermore it's submit but verify, so there
4 will be site visits of all of these centers of
5 excellence for which they are paying to be a
6 center of excellence. And from that step, we're
7 hoping to go forward with mandatory data
8 submission and this is a hope, for membership in
9 the society, that if you want to be a clinical
10 member of the society you must submit your data,
11 which is the next step where we would like to go.

12 And in having been with you at the AHRQ
13 meeting, we would want to work with Carolyn Clancy
14 and want to develop this, and with Medicare to
15 push forward and to get these data, because we
16 need these data desperately for all of the reasons
17 that everybody here has mentioned, whether it be
18 adolescents, whether it be 65 and over, or whether
19 it be the entire population, whether it be this
20 procedure, that procedure, or what procedure, we
21 need more data. We have a lot of data, we never
22 can get enough. And so that's where I think we
23 would be supportive of where you would like to go.

24 DR. DAVIS: Yes, please.

25 DR. KRAL: I want to draw the attention

1 to two studies that are directly pertinent to what
2 you're asking. First of all, in the SOS study
3 where access is not an issue, access is equal for
4 everybody more or less, the patients electing, and
5 they're electing to have surgery, have worse
6 disease than the controls, and everything is being
7 done to try to match them and it has been matched,
8 but the patients electing to have surgery are
9 worse off than those, at the same body mass index,
10 who elect not to have the surgery.

11 In other words, it is a step for
12 somebody to say I'm going to have surgery, it
13 sounds like the easy way out, as if there's going
14 to be a mission creep downward, the woodwork
15 effect, so there is data of that kind showing that
16 it's the more ill people who are going to elect to
17 have and request the surgery.

18 The other piece of data that I want to
19 give you is a paper by Fitzgibbons and coworkers
20 from the early '80s. I started to interest myself
21 in the selection process very early, as I
22 mentioned before. That demonstrates that people
23 wanting treatment for their obesity have different
24 personality characteristics among other things,
25 and different characteristics than the population,

1 everything else equal, not seeking treatment. So
2 sure, is there a selection bias in that? Yes,
3 there is a self selection bias in that, but I'm
4 not so sure that it's a hazardous one.

5 DR. DAVIS: Dr. Weissberg.

6 DR. WEISSBERG: I just wanted to
7 mention in terms of the social networks that are
8 promoting perhaps new populations coming into this
9 consideration for surgery, in our technology
10 committee we were looking at one of the edges of
11 the bubble that was referred to, doing these
12 procedures in adolescents. Not that many people
13 reported on it, but one of the most amazing facts
14 was that of the adolescents in one survey, fully
15 25 percent of them had a family member who had had
16 a similar procedure. And I think that in addition
17 to going to anonymous sources on the Internet,
18 people are going to be developing more and more
19 actual contact and experience with how it has been
20 life transforming and/or hazardous in people
21 around them.

22 DR. DAVIS: Dr. Buchwald.

23 DR. BUCHWALD: If I could just get back
24 to that point that Dr. Goodman made, you're
25 absolutely correct. This is the way of life.

1 When people start, and having lived long enough I
2 have some sense of history, when people started
3 doing angioplasties, they said the same thing,
4 where is this going to go. And before then when
5 they did CABGs, where is this going to end up.
6 And pacemakers, and defibrillators, and
7 nontechnical things such as drugs for
8 hypercholesterolemia, there was tremendous debate.
9 Where is this going to go? Half of the population
10 is going to be taking drugs, and they do at this
11 moment.

12 And the standards have been lowered,
13 again as you correctly stated, the standards for
14 what is hypercholesterolemia keep being lowered
15 and the data support that the lowering is
16 justified. So this is a way of life in anything
17 in medicine. But I think what is unique is that
18 the group representing the bariatric surgical
19 community, the American Society of Bariatric
20 Surgeons that has now formed the centers of
21 excellence project and the testing organization to
22 do this says we're going to police this, and we're
23 going to provide more and more data. I think that
24 is different about the bariatric community than
25 some of the other communities that have come forth

1 with new procedures, or several procedures and so
2 on.

3 DR. DAVIS: Dr. Goodman.

4 DR. GOODMAN: And in all cases, Dr.
5 Buchwald, that you mentioned about the wide use of
6 technologies, and you picked some very good ones,
7 to my knowledge they were all supported by
8 rigorous studies, randomized controlled trials.
9 I'm thinking of coronary artery stents,
10 defibrillators, pacemakers, the treatments for
11 hypercholesterolemia, the legion of RCTs
12 supporting expansion indications for those is well
13 known. And my concern is in trying to help
14 support Medicare be a prudent decision maker, and
15 doctors and patients to make those decisions, will
16 they have that type of data to support their
17 decisions when they are faced with an opportunity
18 to do a procedure with some indications that are a
19 little bit different. And we know that.

20 It sounds like we've stopped doing RCTs
21 in this area for quite some time now, and we know
22 precious little about the elderly Medicare
23 population and that's who we're going to see in
24 this what I referred to as indication creep. So I
25 agree with the phenomenon. I'm suggesting that we

1 help support Medicare and patients and doctors to
2 get the data to make these decisions.

3 DR. BUCHWALD: Unfortunately, we're not
4 going to have too many opportunities to do
5 randomized clinical trials using a real control
6 group, namely obese patients who are not going to
7 be treated. We're just not going to be able to do
8 that. We've tried it. We've tried it for 30
9 years. The patients don't stay in the control
10 group, they cross over. We're going to have to
11 come to our conclusions in another manner.

12 We all agree randomized controlled
13 trials is a wonderful thing and has been put forth
14 as a gold standard, which in a sense it is. And
15 because of that, if you look in our meta-analysis
16 paper, there's table nine, I believe, that takes
17 the five randomized trials in this field and says
18 are they any different than the 22,000 patients
19 that we looked at, and the 134 studies that we
20 looked at, and the answer is no. In other words,
21 the few randomized trials, the small handful we
22 have, gave the same data as the overall
23 meta-analytical assessment.

24 DR. GOODMAN: Let's get some data.
25 Let's set up some systematic fashion to get some

1 data for this emerging population.

2 DR. DAVIS: Dr. Weiner.

3 DR. WEINER: I have a question and
4 comment, one that wouldn't have been possible
5 until Barbara's question. You know, in reading
6 the literature very carefully as I did as a
7 non-physician, but trying to take the evidence
8 base as well as the public health perspective, I
9 too wondered about, you know, which of the now six
10 different classes, and it's actually more than
11 six, as you know, there are even more subvariants
12 out there, and the literature didn't suggest one
13 was better. You experts have also suggested that
14 it's not clear cut that one is better. All right,
15 that's the output side, the outcomes in terms of
16 mortality and morbidity, and granted, there's some
17 preference. But what about the inputs, the costs,
18 the training? Dr. Buchwald has convinced me that
19 we do have a public health problem and I would
20 like to back up and look at the whole issue of
21 obesity and prevention, et cetera, but that's out
22 of our sphere, so I won't do that. I'll just
23 focus on the issue, what did you say, two million
24 people potentially needed the surgery and we're
25 doing 140,000 a year?

1 DR. BUCHWALD: Conservative, two
2 million are eligible.

3 DR. WEINER: Well, are there not great
4 implications of which of the six or 12 different
5 procedures we pick in terms of ramping up and cost
6 benefit? Now we're not allowed to look at cost in
7 terms of does the evidence suggest this procedure
8 has a positive impact, and I'm prepared to vote as
9 many will on that question in a moment. But here
10 we have several that may lead to very similar if
11 not identical outcomes. So therefore, you know,
12 we're not going to be in a position to ask for
13 what is the cost of this procedure versus that
14 procedure, not just for the surgeon, but the
15 entire market basket of services as well as
16 output.

17 But obviously the field needs to
18 address that if we're ever going to hope to answer
19 the types of questions, the woodwork effect
20 questions as well as Medicare as a prudent buyer.
21 And I'm sure that Kaiser and some of the
22 international settings that do ask these questions
23 probably have begun to address it, but I encourage
24 all of you, particularly as we ramp up these
25 databases, to ask these hard questions. The

1 trainers, you know, which is easier to train if
2 we're going to double, triple output of training.
3 Some are harder than others. The outputs may be
4 the same, but difficult questions, and perhaps we
5 can address a few of them today, but I think we're
6 really talking more into the future.

7 There are differences in costs,
8 correct, and training implications of these six
9 different classes? And if the outputs -- was that
10 not really? All about the same?

11 DR. FISCHER: I think the key to many
12 of the questions that have been raised here lies
13 in programs. If you're going to train people for
14 a certain period of time, let's say for a year,
15 and most of the time in a well set-up situation
16 they are going to have the ability to do four,
17 five, sometimes six. I think the exception may be
18 that in certain parts of the country, in certain
19 institutions, that the duodenal switch is not
20 often performed, and that may be the procedure
21 which is not as often performed, but for the
22 others it should be possible to train people well
23 and then have follow-on with proctoring and I
24 think the training will be taken care of.

25 DR. WEINER: How about the issue of

1 similar outputs but different input costs? I
2 don't know if you're the right one to answer that
3 question.

4 DR. FISCHER: Do you want to translate
5 that ?

6 DR. WEINER: In other words, the number
7 of days in the hospital, the types of level of
8 staff that you need for the different procedures,
9 inpatient days.

10 DR. FISCHER: Well, I think there are a
11 number of different criteria. I think with
12 clinical pathways, I think if the clinical
13 pathways are well worked out and people meet the
14 criteria of what a program should look like,
15 they're probably not terribly different between
16 for example the lap Roux-En-Y gastric bypass, a
17 little shorter length of stay than the open. The
18 lap band is one day, all's well the next morning
19 and home you go.

20 So there really is a difference in
21 length of stay, there may be a trade-off as far as
22 the rapidity of weight loss. I think one thing
23 that nobody has mentioned today, and I thought the
24 anesthesiologists that got up was going to mention
25 it, is that my own feeling is that just as we have

1 for example an anesthesia team for cardiac
2 surgery, we have an anesthesia team for
3 transplants, we have an anesthesia team for
4 neurosurgical oncology.

5 I think one of the things people ought
6 to start looking at, I think we need an anesthesia
7 team, and I'm trying to get this in our
8 institution for the very obese patients who are
9 sick. I mean, you wouldn't take somebody who does
10 pilonidal sinuses all week and send them into a
11 room for anesthesia to put to sleep somebody who
12 weighs 450 pounds. I mean, they have terrible
13 airway problems, and the problems we've had have
14 not been with the surgery, it's been with the
15 airway. So whatever you decide to do, I think
16 whatever standards there have to be for programs
17 really ought to take that into account, which in
18 my experience is part of a source of a problem or
19 potential problem.

20 DR. KRAL: May I make a quick one?
21 Many of put together anesthesia teams who are
22 highly specialized on taking care of the severely
23 obese patients. That is the hallmark of any good
24 program. Dr. Weiner, one issue that has to be
25 mentioned, I don't think we should belabor the

1 approach question, laparoscopic versus non, as I
2 indicated earlier when I spoke, forget that.

3 DR. WEINER: Even with my issue of one
4 being more cost effective or a better value for
5 patient or society, with that issue you believe
6 that --

7 DR. KRAL: That's not an issue, the
8 surgery should be provided laparoscopically in the
9 year 2005, primary procedures. But the thing that
10 you didn't consider that I want to make a plea for
11 is to understand that the outcome for the patient
12 is dramatically different for having a purely
13 restrictive procedure like the laparoscopic band
14 and any of the bypass type operations. They are
15 significantly different. And I have provided
16 these types of operations throughout my career and
17 I have done my utmost to try to educate and get
18 the patients to be educated about the differences
19 between those procedures. And when the patient
20 has a choice, they must have a choice, and they
21 will choose, and they will choose differently, and
22 one size does not fit all. We cannot with a
23 mechanistic technocrat attitude say we're going to
24 choose an air-cooled four-cylinder car. We can't
25 do that.

1 DR. DAVIS: I have a question about
2 waiting lists. Dr. Flum this morning, I don't
3 know if he's still here, maybe somebody else can
4 help me with this. Dr. Flum presented data
5 showing, I believe, that people who had bariatric
6 surgery had a lower mortality rate than people who
7 were on the waiting list for bariatric surgery.
8 And I think Dr. Buchwald also referred to people
9 being put on waiting lists and the access problem
10 that that represents. So for comparing people who
11 have the surgery versus those who are on the
12 waiting lists for the surgery, one wonders how
13 comparable those two groups are, and then that
14 raises the question, well, how are people chosen
15 to get the surgery versus being put on the waiting
16 list? Is this first come first served, or is
17 there some sort of priority scheme that would move
18 people over others and they would jump over others
19 because either they're more sick or less sick?
20 How is that done?

21 DR. PORIES: Well, there are two
22 studies. Our own study is one where we followed
23 the patients who were scheduled for surgery, in
24 other words, they not only met the standards for
25 surgery but were actually scheduled and then were

1 turned down, primarily for insurance reasons.
2 There were a few that were turned down because
3 they changed their mind. The mortality difference
4 was in the group that was operated on, the
5 mortality was 1 percent per year over nine years.
6 In the group that was not operated on, the
7 mortality was 4.5 percent per year, so people do
8 die on the waiting list and the mortality is
9 higher.

10 DR. DAVIS: And you're saying these two
11 groups were probably similar?

12 DR. PORIES: We thought so. Now
13 admittedly, those who got the insurance paid
14 probably may be more adept, may be more nimble,
15 may be more quick in getting insurance coverage,
16 whatever, but that's what we got, it's as good as
17 proof as we could get.

18 DR. DAVIS: Dr. Buchwald, you referred
19 to people on waiting lists. Has this been an
20 issue in your practice, or across the field, how
21 is this prioritization done? If the demand or the
22 number of people who are candidates for the
23 surgery overwhelm the resources to deliver the
24 procedure, how is that dealt with?

25 DR. BUCHWALD: I think the speaker you

1 referred to is Dr. Christeau from Canada. They
2 have about a four-year waiting list. In the
3 United States most of us have one-and-a-half year
4 waiting lists. As a result it's done first come
5 first served with certain exceptions. In our own
6 institution we've done about four or five people
7 who were on the cardiac transplant list and they
8 had bariatric surgery instead of a cardiac
9 transplant, and they survived and they're off the
10 cardiac transplant list. We've had some people
11 with pseudotumor cerebri who were going blind, and
12 we pushed them up on the list.

13 DR. DAVIS: Thank you. Dr. Phurrough.

14 DR. PHURROUGH: If there is this access
15 problem that causes waiting lists around the
16 country and there is an increasing demand that's
17 going to happen, and if the bariatric surgery
18 society is recommending only centers of excellence
19 do the surgery, how do we get rid of the waiting
20 lists? Who is going to do the surgery in
21 Hagerstown, Maryland?

22 DR. PORIES: I'm glad you brought that
23 up, because you know, it's quite different from
24 transplant centers where we have a limited number
25 of organs, and certainly at East Carolina we could

1 do more kidneys if there were more kidneys. In
2 this situation I think we have to be aware that we
3 need to be able to provide the service but provide
4 it with great care. So it's our job to define the
5 centers of excellence with great rigor, but then
6 also help centers achieve that level of rigor by
7 education, better training, putting people there.
8 So we now already have 250 applications that are
9 being processed across the United States and I
10 hope that we can probably double that number to
11 get that work done. But we're not going to
12 identify centers of mediocrity, we're going to be
13 pretty tough about it.

14 DR. SUGERMAN: Walter, how many
15 surgeons are in those 250 centers, do you think?

16 DR. PORIES: Just off the top of my
17 head, about 700.

18 DR. DAVIS: Again, just to interject,
19 another example from my sphere of work in
20 immunization, I remember this situation came up
21 when the CDC was considering recommending
22 varicella vaccination universally for children and
23 they made the recommendation well before Congress
24 had appropriated funds to support the vaccination
25 across the country for public sector immunization

1 programs. But you needed the CDC to make the
2 recommendation in order for Congress to provide
3 the appropriations. So in this case you might
4 need a coverage decision and the increase in
5 demand in order to motivate the training and the
6 multiplicity of centers of excellence in order to
7 accommodate that demand.

8 DR. SUGERMAN: I might add, and maybe
9 Walter, you might address this issue in terms of
10 the private insurance carriers out there are
11 demanding that this be developed, some of them are
12 doing it on their own. I know that you can
13 address Blue Cross Blue Shield of North Carolina,
14 but another issue with regards to access that
15 clearly is out of the purview of what we're
16 talking about today is the growing tendency of
17 private insurance carriers to block access to this
18 surgery. But go ahead, Walter.

19 DR. PORIES: We have had very good
20 support from the Blues in North Carolina, partly
21 because their CEO sits on the board of governors.
22 But he has been very helpful and has said they
23 will delegate their centers of excellence program
24 to us as soon as we're really functioning. We're
25 having similar discussions with four other Blues,

1 we're meeting with the medical director of one of
2 the Big Five in two weeks, so we're getting quite
3 a bit of support, and of course we have to do it
4 right and do it well, but I think this is the way
5 to go.

6 DR. PHURROUGH: How many bariatric
7 surgeons belong to your society now and how many
8 hospitals does that represent?

9 DR. SUGERMAN: I can't answer the
10 second question, but the first question is that
11 there are 1,200 members of the society who are
12 surgeons who are full members of the society.
13 There are an additional group of what are called
14 associate members who haven't achieved the
15 criteria to become full members, and there are an
16 additional 700 allied health members, who are
17 nurses, dietitians, nutritionists, so forth.

18 DR. DAVIS: Yes, please.

19 DR. KNAPP: Just from the standpoint of
20 the question of doing clinical medicine, my
21 question with these waiting lists, and this may be
22 becoming a two-part question, the first part is
23 how much of this waiting list is economic?

24 DR. DAVIS: Versus not big enough
25 supply sort of --

1 DR. KNAPP: Versus shortage of access
2 problem.

3 DR. ALLEN: I can maybe answer that.
4 People on our waiting are people who have come in
5 and established themselves as good surgical
6 candidates and we are waiting to get them on the
7 OR schedule. At my hospital, we have taken a
8 number of measures to streamline, so once the
9 people come in, we weigh them, we make sure they
10 clearly are NIH qualifiers and make sure they're
11 acceptable operative risks. And we also do an
12 insurance verification at that point; if for
13 instance they have Blue Cross of Kentucky, and
14 after listening to the information about the
15 procedures, giving the patient the choice, they
16 may say I want nothing but a band. We say that's
17 going to be a real problem because Blue Cross of
18 Kentucky doesn't cover a band and if you want to
19 go through with the process you have the options
20 of changing your allegiances, trying to appeal
21 this, or paying for it out of your pocket.

22 So I think the short answer to your
23 question is there's a very limited number that are
24 economic. There's not people lined up who just
25 can't wait to get in the operating room, it's

1 really I think in most institutions a problem of
2 getting in for initial visit and before the whole
3 deciding process occurs.

4 The other thing that's important, I
5 think to differentiate, to make sure the panel
6 members know, is that it's not like -- I do a fair
7 amount of general surgery as well. If somebody
8 comes into me and they have I gallstones and they
9 have problems and they need their gall bladder
10 out, you know, if they say I really need it now, I
11 say let's do it tomorrow morning. You can't do
12 this with a bariatric operation. This is the
13 ultimate elective operation; you need to go
14 through a number of processes, psychologic
15 evaluation, nutritional evaluation, as well as
16 getting insurance preapproval prior to doing to
17 ensure payment, not necessarily even to the
18 doctor, just to make sure the patient doesn't get
19 hit with a \$30,000 bill at the end of this because
20 for whatever reason the T wasn't crossed or the I
21 wasn't dotted.

22 DR. STILES: I'd like to follow up in
23 terms of access in terms of economics, and a
24 little bit different slant on it coming from a
25 major payer which is an HMO called Kaiser

1 Permanente. There's a lot of things that I see as
2 the doctor who sees all the patients and knows of
3 all the patients that are referred from northern
4 California to our referral center, and we get at
5 least 200 referrals a month for bariatric surgery.
6 And I would say that certainly we do probably
7 within our region maybe 100 a month. And if you
8 do the math, that means 100 people that we are
9 reviewing and often seeing are not ending up
10 getting the surgery. And you might say, some of
11 our patients might say that's an access problem.

12 But I because of being the person that
13 sees most of them, I will say it's because they
14 are not yet ready. There are stringent things
15 that we make our patients do that is similar to
16 what these other fine surgeons are doing as well
17 in terms of making our patients really healthier
18 for surgery, in terms of their medical
19 comorbidities. Our patients walk before surgery,
20 there's a big thing that we make people do.
21 Before a lot of them will come in on their
22 scooters and I will do everything I can, and I'm
23 called the cheerleader for all the patients, and
24 that's because I believe that we can get them
25 healthier and we can get them safer before

1 surgery.

2 It's not meant as a roadblock, but yet
3 people sometimes will be on their own trajectory.
4 Sometimes they will come in and hear our
5 orientation, they will be ready for surgery in
6 three months even if they have significant
7 comorbidities. Sometimes it takes them a year and
8 a half. Sometimes they come in on their scooters
9 and if at all possible, I'll get them to physical
10 therapy to learn upper body extremity exercises.
11 I'm not going to belabor you with all the
12 different things that are possible to do out
13 there, but a lot of us are doing these things to
14 get our patients healthy for surgery.

15 So that the access time may be a year
16 and a half for one patient, but you know what my
17 patients say, and this is the honest truth, is
18 that when they are ready, they know that they are
19 ready, and that's because they understand what
20 they need to do, and they understand we have done
21 everything possible to insure their loved ones
22 that they are going to be safe for surgery, and we
23 have an extremely very very good record in that as
24 well.

25 And the last thing I'll say is that

1 postoperatively, it's not a simple thing. Luckily
2 at Kaiser, if we want to see a patient or a
3 patient wants to see us, we don't have any problem
4 with that, and we will go to -- sometimes I go out
5 to different centers that are farther away in
6 order to see the patients there postoperatively,
7 and we actively have them back for many different
8 kinds of programs. And I think that having access
9 postoperatively insures you that the surgery that
10 you do will be done to the best way possible and
11 that even if they decide they need another surgery
12 down the line, that that's because that's the
13 appropriate treatment for their severe obesity
14 because really, we're taking care of more than
15 just the surgery, as we have all been talking
16 about. Thank you.

17 DR. DAVIS: I think the intensity of
18 the questioning and the discussion is ebbing a
19 little bit, which probably means that people are
20 getting ready to vote. Dr. Phurrough and I were
21 just whispering to each other a little while ago
22 that if the panel believes that we really don't
23 need to go laboriously through the set of
24 questions for people who are morbidly obese but
25 without comorbidities, we could probably just

1 dispense with that.

2 DR. PHURROUGH: We could probably vote
3 on the first question, and if there isn't a good
4 response, then we wouldn't have to do the rest.

5 DR. MCNEIL: I agree with that. I
6 think we should vote on the first question on the
7 second page and then not vote on the rest of the
8 questions on the second page, depending on the
9 answer.

10 DR. DAVIS: Let's just take any final
11 comments before we do that. Dr. Sugerman, did you
12 want to chime in?

13 DR. SUGERMAN: I was going to vote to
14 dispense with the second page, so that answered my
15 question.

16 DR. DAVIS: Yes, Dr. Weiner.

17 DR. WEINER: I fully agree that
18 dispensing with the second page times 25 is a good
19 idea. However, are there not still some
20 instances, particularly I heard about young
21 Medicaid recipients that really have no other
22 morbidities at that time, even if you look real
23 hard, they don't? Therefore, by not voting, have
24 we excluded them for consideration?

25 DR. PHURROUGH: You're going to vote on

1 the first question, my assumption is, on the
2 second page, which says we could not find any
3 evidence with which to answer the rest of the
4 questions, which is not necessarily relevant to
5 what we eventually do with patients who may not
6 have comorbidities.

7 DR. WEINER: So we can't vote on the
8 evidence if there isn't any/.

9 DR. PHURROUGH: Yeah.

10 DR. DAVIS: Yes, Mike.

11 DR. ABECAASSIS: I wanted to echo your
12 concern, because I think if we answer the first
13 question, and let's say the vote is that the
14 evidence is not overwhelming, you know, if you
15 look at some of the subsequent questions, it asks
16 our judgments as to how likely a good outcome is
17 to be in this setting. So I think that by
18 answering the first question, we may actually be
19 disadvantaging potentially a patient like the one
20 that you just brought up, a younger person that we
21 know is going to get into trouble shortly and that
22 might potentially benefit from the procedure. I
23 just want to make sure, Steve, that we're not
24 doing that by taking this vote.

25 DR. PHURROUGH: The purpose for which

1 we have you here is to tell us what the evidence
2 shows. If in fact the evidence is not there for
3 us to arrive at a conclusion, then there are
4 alternatives that we have as an agency to
5 hopefully insure that that patient population is
6 in fact not disadvantaged. It may be that they
7 are not disadvantaged by continuing our current
8 coverage because there is no evidence to change
9 that. Or it may be as we've had the discussion
10 that we're never going to get that information in
11 the current clinical trial setting and so we may
12 do as we have done in other decisions recently,
13 say coverage in this particular entity is only
14 reimbursable if we're collecting data at the same
15 time. And so we can define criteria by which
16 someone who "has no comorbidities" may in fact be
17 able to have surgery but to protect that patient
18 we are only going to do it in the context of some
19 kind of trial to obtain clinical data.

20 DR. DAVIS: Any other final requests or
21 comments before we move to vote? If not, Kim, I
22 think has some instructions that she will provide
23 about voting.

24 MS. LONG: For the record, the voting
25 members present for today's meeting are

1 Dr. Barbara McNeil, Dr. David Margolis, Dr. Cliff
2 Goodman, Dr. Brent O'Connell, Dr. Jonathan Weiner,
3 Dr. Jed Weissberg, Dr. Michael Abecaassis, Dr.
4 Kieren Knapp, and Dr. William Owen. A quorum is
5 present and no one has been recused because of
6 conflicts of interest, and at this time Dr. Davis
7 can call for a motion to vote.

8 DR. DAVIS: Is there a motion to vote?

9 DR. GOODMAN: So move.

10 DR. DAVIS: Second?

11 DR. MCNEIL: Second.

12 DR. DAVIS: Any objection to voting?

13 (No response.)

14 DR. DAVIS: If not, we will proceed
15 with voting. Now, we probably need to talk about
16 the cards and how we're going to do this.

17 DR. PHURROUGH: Everyone has a pack of
18 cards.

19 DR. DAVIS: Right. So the request is
20 that everybody vote whether they're a voting
21 member or not, and we don't want to disenfranchise
22 anybody at the table.

23 The first set of questions pertains to
24 obesity patients with one or more comorbidities,
25 and question number one is: How well does the

1 evidence address the effectiveness of bariatric
2 surgery in the treatment of obesity in patients
3 with one or more comorbidities compared with
4 nonsurgical medical management? And the response
5 choices range from one for poorly up to five for
6 very well. And so, we'll ask each person to pull
7 out their number and hold it up so that Kim can
8 record them.

9 (Dr. McNeil, Dr. Weissberg, Dr.
10 Abecaassis, Dr. Knapp, Dr. Owen, Dr. Raab, Dr.
11 Klein, Dr. Buchwald and Dr. Sugerman voted five;
12 Dr. Margolis, Dr. Goodman, Dr. O'Connell and Dr.
13 Weiner voted four.)

14 DR. DAVIS: Thank you. Question number
15 two is: How confident are you in the validity of
16 the scientific data on the following outcomes?
17 And we will have four votes for this question, and
18 the answers from one for no confidence up to five
19 for high confidence, and first is for sustained
20 weight loss.

21 (Dr. McNeil, Dr. Weissberg, Dr.
22 Abecaassis, Dr. Knapp, Dr. Owen, Dr. Raab, Dr.
23 Klein, Dr. Buchwald and Dr. Sugerman voted five;
24 Dr. Margolis, Dr. Goodman, Dr. O'Connell and Dr.
25 Weiner voted four.)

1 DR. DAVIS: Kim was just reminding me
2 that we will post the results at the end of the
3 meeting on the screen. The next is long-term
4 survival.

5 (Dr. Raab, Dr. Buchwald and Dr.
6 Sugerman voted five; Dr. McNeil, Dr. O'Connell,
7 Dr. Weissberg, Dr. Abecaassis, Dr. Knapp, Dr. Owen
8 and Dr. Klein voted four; Dr. Margolis, Dr.
9 Goodman and Dr. Weiner voted three.)

10 DR. DAVIS: Got it. The next is
11 short-term mortality.

12 (Dr. McNeil, Dr. Raab, Dr. Klein, Dr.
13 Buchwald and Dr. Sugerman voted five; Dr.
14 Margolis, Dr. Weiner, Dr. Weissberg, Dr. Knapp and
15 Dr. Owen voted four; Dr. Goodman, Dr. O'Connell
16 and Dr. Abecaassis voted three.)

17 DR. DAVIS: The next is comorbidities.

18 (Dr. Abecaassis, Dr. Knapp, Dr. Raab,
19 Dr. Klein, Dr. Buchwald and Dr. Sugerman voted
20 five; Dr. Margolis, Dr. Goodman, Dr. O'Connell,
21 Dr. Weiner, Dr. Weissberg and Dr. Owen voted four;
22 Dr. McNeil voted three.)

23 DR. DAVIS: Got it, thank you.
24 Question number three, how likely is it that
25 bariatric surgery, including RYGBP, banding, and

1 BPD, will positively affect the following outcomes
2 in obese patients with one or more comorbidities
3 compared to nonsurgical medical management, with
4 the response choices ranging from one, not likely,
5 to five, very likely. First for weight loss.

6 (Dr. McNeil, Dr. Goodman, Dr.
7 O'Connell, Dr. Weiner, Dr. Weissberg, Dr.
8 Abecaassis, Dr. Knapp, Dr. Owen, Dr. Raab, Dr.
9 Klein, Dr. Buchwald and Dr. Sugerman voted five;
10 Dr. Margolis voted four.)

11 DR. DAVIS: Next, long-term survival.

12 (Dr. Abecaassis, Dr. Raab, Dr. Buchwald
13 and Dr. Sugerman voted five; Dr. McNeil, Dr.
14 O'Connell, Dr. Weissberg, Dr. Knapp, Dr. Owen and
15 Dr. Klein voted four; Dr. Margolis and Dr. Goodman
16 voted three.)

17 DR. DAVIS: Next is short-term
18 mortality.

19 (Dr. McNeil, Dr. Raab, Dr. Buchwald and
20 Dr. Sugerman voted five; Dr. Margolis, Dr. Weiner,
21 Dr. Weissberg, Dr. Owen and Dr. Klein voted four;
22 Dr. Goodman, Dr. O'Connell, Dr. Abecaassis and Dr.
23 Knapp voted three.)

24 DR. DAVIS: Next is comorbidities.

25 (Dr. McNeil, Dr. Goodman, Dr.

1 O'Connell, Dr. Weiner, Dr. Abecaassis, Dr. Knapp,
2 Dr. Raab, Dr. Klein, Dr. Buchwald and Dr. Sugerman
3 voted five; Dr. Margolis and Dr. Weissberg voted
4 four; Dr. Owen voted three.)

5 DR. DAVIS: Thank you. Question four:
6 How confident are you that the following bariatric
7 surgeries will produce a clinically important net
8 health benefit in the treatment of obese patients
9 with one or comorbidities? And there is a
10 definition of net health benefit in the glossary
11 at the bottom of the page as a reminder, balance
12 between risks and benefits, including
13 complications of surgery. Response choices range
14 from one for no confidence up to five for high
15 confidence, and we'll have six votes for question
16 four. The first one is for RYGPB open.

17 (Dr. McNeil, Dr. O'Connell, Dr. Klein,
18 Dr. Buchwald and Dr. Sugerman voted five; Dr.
19 Margolis, Dr. Goodman, Dr. Weiner, Dr. Weissberg,
20 Dr. Abecaassis, Dr. Knapp, Dr. Owen and Dr. Raab
21 voted four.)

22 DR. DAVIS: Okay. Why don't we go row
23 by row, and we'll do RYGBP lap next.

24 (Dr. McNeil, Dr. O'Connell, Dr.
25 Weissberg, Dr. Abecaassis, Dr. Knapp, Dr. Raab,

1 Dr. Klein, Dr. Buchwald and Dr. Sugerman voted
2 five; Dr. Margolis, Dr. Goodman, Dr. Weiner and
3 Dr. Owen voted four.)

4 DR. DAVIS: Next is BPD open.

5 (Dr. Klein, Dr. Buchwald and Dr.
6 Sugerman voted five; Dr. McNeil, Dr. Margolis, Dr.
7 Goodman, Dr. O'Connell, Dr. Knapp, Dr. Owen and
8 Dr. Raab voted four; Dr. Weiner, Dr. Weissberg and
9 Dr. Abecaassis voted three.)

10 DR. DAVIS: Next is BPD lap.

11 (Dr. Abecaassis, Dr. Knapp, Dr. Raab,
12 Dr. Klein, Dr. Buchwald and Dr. Sugerman voted
13 five; Dr. McNeil, Dr. Margolis, Dr. Goodman, Dr.
14 O'Connell, Dr. Weiner and Dr. Weissberg voted
15 four.)

16 DR. DAVIS: Next is banding open.

17 (Dr. Klein, Dr. Buchwald and Dr.
18 Sugerman voted five; Dr. Margolis, Dr. O'Connell,
19 Dr. Weiner, Dr. Owen and Dr. Raab voted four; Dr.
20 McNeil, Dr. Goodman, Dr. Weissberg and Dr. Dr.
21 Knapp voted three; Dr. Abecaassis voted two.)

22 DR. DAVIS: Last is banding lap.

23 (Dr. Abecaassis, Dr. Raab, Dr. Klein,
24 Dr. Buchwald and Dr. Sugerman voted five; Dr.
25 Margolis, Dr. O'Connell, Dr. Weissberg, Dr. Knapp

1 and Dr. Owen voted four; Dr. McNeil, Dr. Goodman
2 and Dr. Weiner voted three.)

3 DR. DAVIS: Thank you. Question five:
4 Based on the scientific evidence presented, how
5 likely is it that the results of bariatric surgery
6 in obese patients with one or more comorbidities
7 can be generalized to the Medicare population aged
8 65 and older? The response choices ranging from
9 one, not likely, to five, very likely.

10 (Dr. Klein, Dr. Buchwald and Dr.
11 Sugerman voted five; Dr. Weissberg, Dr.
12 Abecaassis, Dr. Knapp and Dr. Raab voted four; Dr.
13 Margolis and Dr. Owen voted three; Dr. McNeil, Dr.
14 Goodman, Dr. O'Connell and Dr. Weiner voted two.)

15 DR. DAVIS: And 5.B, the same question,
16 can be generalized to providers (facilities/
17 physicians) in community practice.

18 (Dr. Buchwald and Dr. Sugerman voted
19 five; Dr. Klein voted four; Dr. McNeil, Dr.
20 Margolis, Dr. Goodman, Dr. O'Connell, Dr. Weiner,
21 Dr. Weissberg, Dr. Abecaassis, Dr. Knapp and Dr.
22 Raab voted three; Dr. Owen voted two.)

23 DR. DAVIS: Thank you. And we will
24 begin with the next set of questions and see how
25 far we get, depending on the outcome of number

1 one, which some might predict the outcome of. So,
2 this next set of questions is for obese patients
3 without comorbidities. Question number one: How
4 well does the evidence address the effectiveness
5 of bariatric surgery in the treatment of obesity
6 in patients without comorbidities compared to
7 nonsurgical medical management? The response
8 choices range from one for poorly to five for very
9 well.

10 (Dr. Margolis, Dr. Weiner, Dr.
11 Weissberg, Dr. Abecaassis, Dr. Knapp and Dr.
12 Buchwald voted two; Dr. McNeil, Dr. Goodman, Dr.
13 O'Connell, Dr. Owen, Dr. Raab, Dr. Klein and Dr.
14 Sugerman voted one.)

15 DR. BUCHWALD: So as we were discussing
16 before, if the panel is comfortable with this and
17 if CMS is comfortable with this, based on the
18 results from question number one for obese
19 patients without comorbidities, we can dispense
20 with the remainder of the questions. Is there
21 general assent among the committee members? And
22 Dr. Phurrough, on behalf of CMS, you're happy with
23 that?

24 DR. PHURROUGH: The committee has
25 spoken.

1 DR. WEINER: As long as the record
2 shows our concern.

3 DR. DAVIS: That's right. And of
4 course the full discussion has been transcribed,
5 will be available to CMS, will be posted on the
6 web, and so I think the committee's sentiments
7 about this will be part of the record. Yes, Mike?

8 DR. ABECAASSIS: You don't think it's
9 worth restating the concern as a matter of public
10 record?

11 DR. DAVIS: What we should do now is as
12 is customary for MCAC, is to go around the table
13 and allow each person to make whatever comments he
14 or she would like to explain his or her votes.
15 And that would provide an opportunity to express a
16 concern like the one you were referring to. So
17 why don't we proceed with that now, so Barbara,
18 sorry to pick on you.

19 DR. MCNEIL: So, I guess I usually, I
20 sometimes vote a little harder than I did this
21 time, I am told, but I was really quite impressed
22 with the data, so I thought that the outcomes were
23 fairly clearly and effectively improved by the
24 various kinds of surgeries. I was less, really
25 less able to make decisions among the six

1 different types and that's why my votes went down.
2 And I didn't see any data whatsoever that made me
3 think that I could be absolutely certain that
4 these very same results would apply to the
5 Medicaid population over 65, or the providers at
6 large without a significant amount of monitoring
7 or training.

8 This looked to me like a good situation
9 where the data looked pretty compelling for lots
10 of situations, but to go forward whole hog, we
11 really have to think critically about what we're
12 going to do about monitoring, how we're going to
13 define the patient populations better, how we're
14 going to define the sites better, and it seems to
15 me there are a slew of ancillary questions that
16 CMS will have to think about that go way beyond
17 the specific questions that we voted on just now.

18 DR. MARGOLIS: I don't really have all
19 that much more to add other than I think the data
20 has been well summarized multiple times already.
21 I mean, those summaries are available I guess
22 publicly, and they were reviewed and discussed
23 today. My one overriding concern is just how the
24 patients were selected who had the current
25 procedures, and how that's going to influence the

1 outcomes in the future, but there's really no
2 great way to answer that right now with the
3 exception of perhaps the Sweden study, so you will
4 need to evaluate as you go forward.

5 DR. GOODMAN: And for most of these
6 questions, the preponderance of the evidence
7 outweighed the lack of rigor by which the evidence
8 was generated, so historically a big body of
9 evidence was built up, it wasn't built up in a
10 very rigorous way. If we had to do it all over
11 again, there's probably a better way of doing it,
12 but at this point it built up to be largely
13 persuasive.

14 The second point is that we need to
15 establish the capacity to capture the data for the
16 emerging populations of indication creep, which is
17 inevitable.

18 DR. O'CONNELL: A couple of things. I
19 have some reservations about the short-term
20 morbidity and mortality, I think it's
21 significantly under reported and I think we'll
22 find as we go forward it's going to be a little
23 higher. I like the data but I, again, did not
24 find anything to suggest we could move this to the
25 Medicare age group. I'm also a bit worried that

1 the community is not ready to take on the load, as
2 evidenced by the limited number of facilities,
3 certainly in my state, that are capable of doing
4 this major surgery. So, I'll just leave it at
5 that.

6 DR. WEINER: Again, I too underscore
7 everything that's been said, and just add a few
8 things. The provider community seems to be very
9 advanced in its thinking about quality and
10 evidence base and data collection, and I urge you
11 to continue in that way hopefully with some
12 cajoling from CMS. And the vote, my vote and
13 everyone's vote was very low on the over 65; that
14 clearly must be a priority in terms of emphasize,
15 because there was some suggestion in some of the
16 literature that there could be some
17 counterbalancing negatives for that population.

18 I also do believe that the focus here
19 today and the focus of most of you is one
20 procedure, a few clear set of outcomes on a
21 patient who has clear-cut need, but we will need
22 to step back, and two issues I raise. One is the
23 broader, how this fits in with the broader
24 preventive in medical, and again, that wasn't our
25 charge today, but I know most of you focus on

1 that. It should be and will be Medicare's charge,
2 I know the administration here for four years more
3 makes that a high priority, and kudos to them for
4 that.

5 And then also the issue of training. I
6 think clearly the work force issues which I spent
7 some time on, and surgery and bariatric surgery, I
8 never quite put surgery and public health quite so
9 closely together as perhaps in this case, and I
10 think we must look at that from the broader
11 perspective, again, not exactly Medicare's charge,
12 but Medicare by far is the biggest payer for
13 training in this country, so perhaps the two
14 should go together.

15 DR. WEISSBERG: Sometimes when I walk
16 into my office there's a manila envelope that's
17 taped shut with a confidential stamp on it, and
18 that represents a report of a serious adverse
19 event from somewhere in our health care system
20 that happened to one of our 8.2 million members.
21 Five times in the past year there have been
22 serious adverse events, including deaths, in
23 bariatric surgery patients. Now given that we're
24 doing between 1,000 and 2,000 a year, that's an
25 acceptable level of short-term mortality as judged

1 by what our surgeons reported in the literature.
2 But when I read the details of those cases, I see
3 opportunities for improvement and for driving that
4 level of mortality down even further. So, I'm
5 very concerned about the profession rapidly
6 getting up to gear in terms of policing itself,
7 sharing its knowledge, and standardizing to the
8 point of driving that short-term morbidity and
9 mortality down even further, and I'm very
10 confident that our government will be able to
11 derive data as the population inevitably expands.

12 DR. ABECAASSIS: I guess I just want to
13 say sort of a cautionary note about -- and I
14 understand that our job is to evaluate the data
15 that exists, and make the best recommendations
16 based on the data, but I just want to go on the
17 record by saying that just because the data are
18 not there does not mean that some of these things
19 don't make a lot of sense. And the perfect two
20 examples of that are patients who are truly obese,
21 especially younger patients who are headed towards
22 terrible morbidities that, you know, under the
23 data that exist now, would not be candidates for
24 the procedure.

25 And the second is the population over

1 65. Again, just because there aren't a lot of
2 data on those patients, probably as a result of
3 lack of coverage for certain procedures, we should
4 not take that as meaning that the procedures don't
5 make sense. And the reason that I'm concerned
6 about this is that being in transplantation, I
7 know what it's like to deal with intermediaries
8 who decide on their own what the rules should be.
9 And unless it's clearly stated by CMS, you have
10 tremendous discrepancies in coverage on a
11 geographic basis, and I think that that's wrong.

12 DR. DAVIS: Mike, just to clarify, you
13 might be talking about a young person with a BMI
14 of 36 but no comorbidities?

15 DR. ABECAASSIS: Yeah, that would be
16 it.

17 DR. DAVIS: Thank you.

18 DR. KNAPP: As a practicing rural
19 family doc, the thing important to me is not
20 necessarily all the reams and reams of data that
21 we were given to read, but the overall picture and
22 actually what works for the patients. We've been
23 presented with a number of procedures today, they
24 all seem to work, they all seem to decrease the
25 morbidity and mortalities. I don't think they

1 will resemble anything compared to what we're
2 seeing ten years from now as far as procedures,
3 these may not even exist, but the idea is that it
4 does provide some hope for that. I'm the guy who
5 walks in and has to look at 30 people that are
6 grossly overweight every day in my office.

7 I think one of the problems with the
8 data on the Medicare patients who are over age 65
9 may be because of the morbidities associated with
10 that size and age group, we may have already
11 thinned the herd by the time they've gotten to age
12 65, to use a farm term. I think you're going to
13 see survivability go up remarkably in that age
14 group and I think you will have the data within a
15 number of years for the over age 65 group.

16 DR. OWEN: The area that I want to
17 comment about specifically is external validity of
18 the data. In many ways I have an ongoing concern
19 that we're seeing center-specific effects in terms
20 of what's presented here. I'm often reminded when
21 you go to national meetings and you ask about
22 performance measures like those in the search, you
23 ask the audience, how many doctors prescribe beta
24 blockers for their patients after an MI?
25 Everyone's hand goes up. And I'm fearful that of

1 course you're seeing the same thing in terms of
2 reporting bias in the literature and what's being
3 seen here. In other words, you're seeing best
4 experiences and best clinical practices. As this
5 unrolls, I am fearful we will see exactly what has
6 been seen in every other subspecialty when a new
7 procedure is introduced, and that is the
8 experience in the larger community differs quite
9 substantially from what has occurred in the past
10 and what has been reported, so that's the area of
11 greatest concern.

12 And I recognize that the centers of
13 excellence program is in place, it is admirable,
14 it is wonderful. But I also remind you that there
15 is a wonderful paradigm of quality monitoring and
16 quality improvement which was actually mandated by
17 Congress and CMS in the Medicare program, and
18 that's the end-stage renal disease network program
19 which has been in place now for about 15 years.
20 When data collection began in terms of looking at
21 performance of something as simple as dialyzing
22 someone, 75 percent of the patients were found to
23 have inadequate dialysis. So caution is urged,
24 and likewise, I urge a lot of rigor in terms of
25 making certain your participants adhere to best

1 clinical practices.

2 DR. RAAB: I don't want to repeat what
3 everyone's said about the evidence. I found it
4 compelling that the procedures had real impact
5 compared to nonsurgical interventions, nonsurgical
6 management, but I want to highlight that I was
7 most attentive during Barbara McNeil's queries as
8 to which procedure should be chosen for which
9 patient. I think that's fairly troublesome, and
10 it calls for the need for more long-term
11 information, perhaps registries.

12 DR. KLEIN: I have recently become a
13 geriatrician at my hospital and you know, our
14 population is getting older, and the prevalence of
15 obesity in the elderly population 65 and over is
16 increasing dramatically. Now obesity has become
17 the most important cause of frailty in the elderly
18 and it's a leading cause for nursing home
19 admissions. And so I think having a procedure
20 that's low risk like potentially the gastric
21 banding procedure, that will improve
22 functionality, is critically important, and one of
23 our end points should be not just looking at
24 weight loss and the typical comorbidities in the
25 elderly population, but really their ability to

1 function, which requires a different paradigm
2 completely in looking at outcome measures.

3 DR. BUCHWALD: First of all, I would
4 like to plead that we all work together to provide
5 the missing data ,and I think we shall. And then
6 I just want to thank Medicare for having this
7 conference, for giving a voice to the bariatric
8 surgical community, and for even having some of us
9 sit up here. Thank you.

10 DR. SUGERMAN: I too want to express my
11 thanks and say how impressed I have been with this
12 process, and I hope that the discussions that we
13 have had amongst ourselves and the people who
14 presented will be weighed very carefully by
15 Medicare, and consideration be given to how best
16 to equalize access for all of our patients who
17 need this surgery so desperately across the
18 country.

19 DR DAVIS: Yes, please.

20 DR. RABKIN: Dr. Davis, I want to tell
21 you how impressed I am by the panel, but I did
22 want to do one little pesky thing, which is to
23 clarify for the record the nomenclature, which I
24 believe one of the questions referred to BPD, and
25 the data today that was given referred to the

1 duodenal switch, and it's my belief that the panel
2 members felt that what they were talking about
3 labeled BPD included the duodenal switch.

4 DR. DAVIS: Is there general agreement
5 with that? I see a lot of nodding of heads around
6 the table. Thank you for that clarification.

7 I would just like to extend kudos to
8 members of the committee, CMS staff, and all of
9 the presenters for their outstanding participation
10 in today's proceedings and in the preparation for
11 it, and I will now turn things over to Kim Long
12 and Dr. Phurrough to close off the meeting.

13 DR. PHURROUGH: I want to add my thanks
14 both to committee members who do -- this is not a
15 simple task. We sent you lots of stuff and it was
16 obvious that you spent some time on it, and we
17 appreciate that. I thank the guest panelists for
18 agreeing to be part of this. Our goal is to have
19 good quality clinicians to provide advice to our
20 panelists who in many cases are good
21 methodologists but may not have specific clinical
22 knowledge of the specific process, though we give
23 them enough stuff to learn a good bit about it.
24 So we have a history of doing this and we will
25 continue it.

1 Thanks to all those who showed up to
2 present, both those who were formal presenters and
3 those who chose to present today. I want to
4 specifically thank Dr. Pories for his comment
5 about Mama Michelle here.

6 MS. LONG: Kim.

7 DR. PHURROUGH: Kim, excuse me. Dr.
8 Pories wanted about a couple of hours, in fact
9 he'd like to have had all day, and we just
10 couldn't do it. So there was this back and forth
11 to get down to what we thought was an adequate
12 amount of time, about an hour, 45 minutes to an
13 hour, and you did a superb job in coming down to
14 that. So I think the panel was well served by
15 this interaction that went on to get this down to
16 a small amount of time. But we do appreciate all
17 of those who spent their time and the effort to
18 come and assist us today.

19 Now we have had the question and folks
20 have asked, what's the next step? Well, we have
21 several options. First, it's do nothing. Every
22 Medicare beneficiary today who has any comorbidity
23 and is obese can have surgery, nothing prevents
24 that from happening in our current policy. You
25 meet all the indications, surgeons are competent

1 in doing it, you can do that surgery.

2 Now, we do have various levels of rules
3 that are established by our various contractors
4 and so we could open an NCD and become more
5 specific in our details around who is and isn't
6 covered, more specific around what are the
7 appropriate comorbidities and so forth.

8 We could open a coverage decision and
9 say we're going to cover less, based upon some of
10 the discussions that we've had today, and we could
11 open a coverage decision that says we're going to
12 cover more.

13 So those are all options. So what our
14 expectation internally is that we're going to take
15 the recommendations and the information that has
16 been provided to us today and internally discuss
17 whether in fact we should have some change in our
18 current coverage decision.

19 Now, we in general do coverage
20 decisions, or we initiate coverage decisions in
21 two manners. One is, we decide internally to
22 readdress coverage decisions. The most common way
23 that we change our coverage decisions or have new
24 coverage decisions is someone asks us to do that,
25 and we have a fairly well defined process, you

1 find that on our web site, www.cms.gov/coverage.
2 And anyone, and I mean anyone, from a beneficiary
3 to a provider to a company to an organization, in
4 fact it was CDC who had us remove the obesity
5 language, or who asked us to remove the obesity
6 language, can request that we modify our current
7 coverage process to something else. And so we
8 would certainly be interested in hearing from
9 someone who is interested in us changing our
10 policy. We in fact think that's the best way to
11 do it, because then we have some public interest
12 in having that done and it's always helpful that
13 the public is interested in what we're doing
14 rather than our deciding on our own to do things.
15 That always goes over better with the public.

16 So those are our next processes, and so
17 we will be reviewing this information, though we
18 certainly encourage folks who are interested in us
19 having a different policy to request that we
20 change that.

21 So with that, thank you again for your
22 time, and Kim, you have some final, or Michelle,
23 you have some final comments? I can't even
24 remember who I'm talking to.

25 MS. LONG: I want to thank everyone

1 also, and if somebody would move to adjourn, we
2 can end the meeting.

3 DR. WEISSBERG: Move to adjourn.

4 MS. LONG: Second?

5 DR. O'CONNELL: Second.

6 MS. LONG: We are adjourned.

7 (Whereupon, the meeting adjourned at
8 3:45 p.m.)

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